American Academy of Pediatrics

Department of Government Liaison
American Academy of Pediatrics
The Horner Building
801 Thirteenth Street, NW
Suite 400 North
Washington, DC 20005
202/347-8600
800/336-5475
Fax 202/393-6137

June 26, 1995

Representative Thomas J. Bliley Jr.
U.S. House of Representatives
2241 Rayburn House Office Building
Washington, DC 20515

Dear Representative Bliley:

The American Academy of Pediatrics (AAP) was pleased to testify on May 11, 1995, before the Subcommittee on Health and Environment on HIV testing of women and infants. This is an extraordinarily complex and passionate debate -- one that has been discussed extensively by the membership and leadership of our national organization, which represents over 48,000 physicians. As Congress further contemplates this issue, it is essential they understand the medical, as well as the social and behavioral components of any legislative action.

The HIV/AIDS epidemic is increasing in women of childbearing age and spreading beyond previously defined risk groups and geographic areas. This increase has been reflected by a similar increase in children.

There are now clear medical benefits of knowing the HIV status of pregnant women and newborns. Treatments are currently available to significantly reduce the HIV transmission from mother to infant (zidovudine/AZT.) In fact, the study results which documented the value of AZT in pregnancy can save up to 1000 lives annually and represents the most important medical breakthrough in recent years. In addition, the lives of the small percentage of infants not protected by the AZT treatment can be prolonged infants by initiating medical care within the first months of life in order to reduce infections such as *pneumocystis carinii* pneumonia (PCP).

It is essential that Members of Congress understand that both AZT and PCP medical treatments for women and children require intensive, daily/regular, and prolonged dosages of medication. Compliance with medical care is likely to be greatest when the patient is fully informed and feels she has made an educated judgment regarding HIV testing for herself or her infant. A relationship of respect and trust between women and the health care system is critically important to the identification of women and infants who are HIV-infected and their subsequent care and treatment.

To comprehensively and compassionately address HIV infection in women and infants, it is recommended that all pregnant women receive HIV education and counseling and that they be routinely tested with consent, as part of their part of their prenatal care. For newborns whose mother's HIV status is unknown at birth, it is recommended that they be tested with the consent of their mother.

Testing programs must be confidential, voluntary and accompanied by cultural and ethnically appropriate information regarding HIV infection.

We support utilization of consent procedures that facilitate rapid incorporation of HIV education and testing for women, and infants in the routine medical care setting. Consent may be obtained in a variety of ways and may include documented patient education, with testing to take place unless rejected in writing by the patient.

We caution Congress against imposing unrealistic and negative restrictions on women and infants. We ask that you consider these recommendations as the debate over HIV testing continues in Congress.

Sincerely,

George Comerci, MD

George D. Comerci, MD
President

F

TO: Hillary Rodham Clinton
FROM: Jennifer Klein J.K.
DATE: 6/5/95
RE: Letter to Editor on HIV Testing

The 25% that Dr. Arons refers to is the actual rate of transmission from mother to child. If a woman is HIV positive, there is a 25% chance that her baby will be infected. However, almost all babies born to HIV positive mothers *test* positive at birth because they still have maternal antibodies. Therefore, the initial result is not an accurate test of the HIV status of the baby.

The sentence that you underlined seems to suggest that all states or health care providers be required to offer HIV counseling and testing. The American College of Obstetrics and Gynecology will release guidelines in September that make voluntary counseling and testing the "standard of care" for all pregnant women. This, according to physicians, will effectively serve as a mandate because doctors fear that they will be held libel in a malpractice suit if they do not follow professional guidelines.

cc: Maggie Williams

TO: Hillary Rodham Clinton
FROM: Jennifer Klein J.K.
DATE: 6/28/95
RE: HIV Testing of Pregnant Women and Newborns

Attached please find a memo from Patsy Fleming about the Coburn amendment that we discussed yesterday. I wanted to highlight two things. First, Patsy notes that the Public Health Service meeting on July 11 and 12 is expected to address "what policies are appropriate when neither the mother nor the newborn has been tested voluntarily." Second, the attached letter from the National Governors Association (NGA) points out that the Coburn amendment is overly broad given the geographic concentration of AIDS. According to the NGA, between 1993 and 1994, 63% of all pediatric AIDS cases occurred in only three states; 89% of cases occurred in 15 states.

These two facts give us a solid foundation for pursuing mandatory testing of newborns in "high risk" areas. Jeff Levi in our AIDS office agrees that this is an accepted public health approach. We are working together to develop a strategy.

cc: Melanne Verveer

FYI HRC — MAGGIE To Jean

THE NEW YORK TIMES, FRIDAY, JUNE 30, 1995

ıbia Ignores :s by Military

Editor:

"Colombia Marvels at Drug ɔin: A Chain-Saw Killer, Too?" ʌs article, June 21): You miss a ' point when you turn to Henry ɹiza Ceballos's role with the army ɹd police in what has become ɹnown as the Trujillo massacre, the murder of 107 people in 1990.

These officers were "corrupt." But Maj. Alirio Urueña, who witnesses say dismembered his victims with a chain saw, was also a decorated officer promoted after the killings. Far from "shocking" the Government, the behavior of Major Urueña and his men was covered up until international pressure marshaled by Colombian human rights groups forced authorities to agree to a commission to restudy the Trujillo case.

Only after this commission delivered its findings was Mr. Urueña dismissed.

For the courts, it is far easier to grasp the Scorpion for drug-trafficking than Mr. Urueña, shielded by an institutionalized esprit de corps that defends even forced disappearance — a secret arrest usually followed by execution — as an "act of service." Until Colombia investigates, prosecutes and punishes crimes committed by its own, cases like Trujillo will remain the rule, not the exception. ROBIN KIRK

Research Associate
Human Rights Watch-Americas
Washington, June 21, 1995

The Harm Infant H.I.V. Testing Can Do

To the Editor:

Re "AIDS Babies Deserve Help, Now" (editorial, June 25): The Ackerman-Coburn plan you endorse would make AIDS funding to states contingent on human immunodeficiency virus testing of all babies whose mothers have not accepted voluntary testing during pregnancy. This would force states to choose between violating the rights of pregnant and newly delivered women, or losing funds for the majority of individuals with H.I.V.-AIDS who are not directly involved in this controversy.

Because the H.I.V. test at birth identifies maternal antibodies in the infant, the result would be a profile of the mother's H.I.V. status. The process would thus amount to mandatory testing of all mothers in two stages. If they hadn't volunteered during pregnancy, the result would be obtained through their infant surrogate.

Even without prenatal AZT, only about 25 percent of infants testing H.I.V. positive are truly infected. Does that justify overriding the right to informed consent for the remaining women who declined testing?

Using AZT, the perinatal transmission rate has been reduced to 8 percent. Thus, a better case can be made to require testing of all pregnant women. Unfortunately, involuntary testing could further cause women hesitant to interact with the system to avoid prenatal care altogether.

It would be more constructive to mandate that every pregnant woman be offered voluntary H.I.V. testing with the assurance that if positive, she and her family would be entitled to comprehensive medical, nutritional and social services before, during and after birth.

Women are more likely to accept testing when persuaded that society cares about them, rather than displaying a punitive attitude that devalues the mother in the name of saving the baby. PAUL ARONS, M.D.

Medical Director, Leon County
Public Health Unit
Tallahassee, Fla., June 26, 1995

Talk Radio's Roots

To the Editor:

The Freedom of Speech Award to G. Gordon Liddy at the radio talk show hosts convention should be considered an aberration (Chronicle, June 26). For every Liddy on the far right and every leftish host, there are hundreds of radio talkers who voice no political bent but who host programs of community service and sage advice. They are on 500-watt small-town stations as well as boomers, networks and syndicate.

Talk radio started as "neighboring" in Iowa in the 1920's. Despite the current in-your-face fad, honest content remains a grass-roots ingredient of talk radio. ANNIE BREWER

Dearborn, Mich., June 26, 1995
The writer edits Talk Shows and Hosts on Radio, an annual directory.

Even Before Medicare Cuts, Health Care System Has Changed

To the Editor:

Re your June 26 front-page news analysis on changes in the health care system as a byproduct of budget cutting: The important point you make is that while the proposed slowdown in Medicare and Medicaid spending, which accounts for almost one-third of total health care spending in this country, will probably have a major impact on our health care system, nobody is sure yet just how that impact will play out.

The point you miss is that the train has already left the station. Profound changes in our health care system are already under way, precipitated not by changes in government policy (since these haven't occurred), but by dramatic changes in the purchasing behavior of private employers, whose spending for employee coverage accounts for most of the remaining two-thirds of health care spending.

Beginning in the late 1980's, large private employers, looking to increase productivity and streamline production costs (which include employee benefits), began aggressively exercising their purchasing power in the health insurance market, forcing down premium costs and triggering a transformation of the health care delivery system into a bewildering array of new provider networks.

If we want to get some idea of how the proposed slowdown in Medicare and Medicaid spending might play out — and how to minimize the risk to beneficiaries — we should pay much closer attention to the changes that have occurred in response to the slowdown in private spending.

In part because for two years all eyes were on the health care reform debate in Washington, many of us have missed what's going on in our own backyards. PAUL S. JELLINEK

Princeton, N.J., June 26, 1995
The writer is a vice president of the Robert Wood Johnson Foundation.

Illegal Parkers

To the Editor:

Re Joyce Purnick's June 22 column on illegal parking in New York City: Doctors and reporters are limited to parking at specially marked areas during working hours only. In my neighborhood all the unticketed, illegally parked cars belong to police officers and judges: the people charged with enforcing the law.

Of course, they may not have Health and Hospitals Commissioner Maria Mitchell's connections and have parking tickets dismissed (news article, June 25). This arrogance of power needs to be further investigated. THOMAS L. FABRY, M.D.

New York, June 26, 1995

Detention Under Study

To the Editor:

Re "The Lessons of Esmor" (editorial, June 21): You believe that the Attorney General should appoint a commission to study the Immigration and Naturalization Service's detention policies. Congress has already done so; addressing detention and removal policies are part of this commission's comprehensive mandate.

In our first report to Congress last year "U.S. Immigration Policy: Restoring Credibility," the bipartisan United States Commission on Immigration Reform recommended more effective policies for the removal of criminal aliens. We are undertaking a review of other issues related to deportation, including detention of aliens. The report will be available this year. SUSAN MARTIN

Executive Director, United States Commission on Immigration Reform
Washington, June 23, 1995

PHOTOCOPY
HRC HANDWRITING

? is this [illegible] there [illegible] push-ups? or what

OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

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

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

FACSIMILE COVER SHEET

TO: The First Lady

FAX NUMBER: 456-6244

FROM: Patricia Fleming

DATE: June 27, 1995

PAGES INCLUDING COVER SHEET: 6

COMMENTS:

THE WHITE HOUSE

WASHINGTON

June 27, 1995

MEMORANDUM FOR LEON PANETTA

FROM: Patricia Fleming

SUBJECT: Amendment to the Ryan White CARE Act on Mandatory HIV Testing

cc: The First Lady

Summary

The House Commerce Committee today postponed full committee consideration of the reauthorization of the Ryan White CARE Act on Tuesday because of controversy surrounding a proposed amendment by Rep. Tom Coburn (R-OK) to require all states to mandate HIV testing for certain newborns. Coburn's amendment would:

- Endorse as the standard of care "mandatory counseling and voluntary testing of pregnant women" (the policy recommended by the Public Health Service);
- Require, as a condition of receiving certain Ryan White CARE Act funds, that each State have a law requiring HIV testing of newborns in cases where the HIV status of the mother is unknown;
- Forbid the use of HIV status to terminate or alter the terms of health insurance.

The amendment had broad support among Republicans on the Committee and may have been supported by many of the Democrats. However, the National Governors' Association sent a letter (attached) opposing the amendment on the grounds that this was an unfunded mandate. This caused the delay in the markup. All the major AIDS organizations opposed the Coburn amendment, as did the Association of State and Territorial Health Officials and the National Alliance of State and Territorial AIDS Directors. It is quite possible that the Committee's leadership will seek to delay consideration of Coburn's proposal while moving forward with the Ryan White reauthorization.

Background

The Coburn amendment is part of a long-simmering debate over mandatory testing of pregnant women and mandatory testing of newborns. As you know, in February 1994, NIH-funded researchers reported the groundbreaking results that the use of AZT during pregnancy, labor, and childbirth can reduce the risk of HIV transmission from mother to child by as much as two-thirds. This is the first time we have been able to block

transmission of HIV with a drug.

As a result of this finding, the Public Health Service, in consultation with outside experts, developed new guidelines recommending that doctors counsel all pregnant women to accept voluntary HIV testing. Doctors should then 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 given birth but who have not been tested should be counseled and offered voluntary testing for themselves and their newborns before leaving the hospital. These guidelines, issued in draft form for public comment, have drawn strong support from medical, public health, and ethics groups. They will be issued in final form on July 7th. One of the provisions in the Coburn amendment endorses the guidelines' recommendation that prenatal HIV testing be voluntary.

Since all babies carry their mothers' antibodies at birth, a test of a newborn simply reflects the mother's HIV status -- not the necessarily the newborn's own HIV-status. However, it is possible to treat all babies whose mothers are HIV positive to prevent certain AIDS-related conditions. In April 1995, CDC issued expanded guidelines that recommended antibiotic treatment of all babies born to HIV-positive women to prevent Pneumocystis carinii pneumonia, a major killer of HIV positive babies. Until April, the standard of care had been to treat only those babies whose immune systems were compromised.

Coburn Amendment and Administration Policy

The intent of the Coburn amendment, developed with Rep. Gary Ackerman, is to assure that newborns be tested when the HIV status of the mother is unknown. This proposal is less extensive than one introduced earlier Ackerman, which would have unblinded the now-suspended CDC seroprevalence study of newborns. It also rejects earlier calls for mandatory testing of all pregnant women.

This support of voluntary prenatal testing makes it incumbent upon the Administration to assure access to counseling and testing and to AZT therapy for pregnant women. My office and the relevant HHS agencies have been working closely to develop a strategy that integrates voluntary prenatal testing into all programs that reach women at risk for HIV. Some of these steps are already in place. For example, HCFA has mandated the coverage of AZT for HIV-infected pregnant women under the Medicaid program. Other efforts are ongoing, such as the training of providers in proper counseling regarding HIV and AZT therapy. Still other issues need to be resolved, as in Medicaid coverage of HIV counseling and testing.

The Administration has taken no position on this amendment. The amendment is, however, in part a strong endorsement of the voluntary approach to prenatal testing that is central to the PHS guidelines. The PHS is sponsoring a meeting on July 11 and 12 of outside experts

and community groups to discuss these issues in greater depth. Following that meeting, PHS will develop recommendations for any additional steps to achieve voluntary prenatal testing, and broader access to prenatal treatment with AZT. PHS will also grapple with the most difficult part of the strategy, which is what policies are appropriate when neither the mother nor the newborn has been tested voluntarily. It is at this point that the Administration will have an opportunity to weigh in on this debate -- in advance of final consideration of any legislative action on this or related proposals.

NATIONAL GOVERNORS ASSOCIATION

Howard Dean, M.D.
Governor of Vermont
Chair

Tommy G. Thompson
Governor of Wisconsin
Vice Chair

Hall of the States
444 North Capitol Street
Washington, D.C. 20001-1512
Telephone (202) 624-5300

June 26, 1995

Representative Thomas Billey
Chairman
Committee on Commerce
Room 2125
Rayburn House Office Building
Washington, DC 20515-6065

Dear Chairman Billey,

On behalf of the nation's Governors, I am writing to express our opposition to the proposed amendment to H.R. 1872 that will be offered by Congressman Coburn tomorrow. Mr. Coburn's amendment would make AIDS funding to states under the Ryan White Care Act contingent upon passage of state laws requiring the mandatory testing of all newborns for HIV disease.

This amendment is antithetical to both the unfunded mandates legislation passed just several months ago and the Congressional trend toward a less prescriptive federal government. Regarding the former, while the amendment is silent on funding for mandatory testing and counseling, one must assume that this will be paid either by the state directly or passed on to insurers or individuals. If Congress is interested in establishing policy with financial impact, it should be willing to pay the cost. If this is to be paid by CARE Act funds, significantly less will be available for treatment of persons with AIDS.

This proposal is an important example of why broad federal prescriptions must be considered carefully. According to the Centers for Disease Control and Prevention, between 1993 and 1994, 63 percent of all pediatric AIDS cases occurred in only three states; 89 percent of cases were in 15 states. And while pediatric AIDS is a subset of HIV disease, we believe that HIV disease has a similar distribution among states. This amendment chooses to establish a national screening and counseling program with significant costs for all states when the problem appears more focused in a much smaller number.

The National Governors' Association supports the reauthorization of the Ryan White CARE Act; however, the Association has no position on mandatory testing for HIV. As such, this letter should not be interpreted as addressing the strengths or weaknesses of mandatory testing and counseling. However, denying states access to important federal funds that are essential for the care of persons with AIDS in order to establish a new federal requirement is not good public policy.

If you have any questions, please feel free to contact Carl Volpe of my staff who would be happy to answer any of your question.

Sincerely,

Raymond C. Schuppach
Executive Director

cc: Representative John D. Dingell
Commerce Committee Members

TO: Hillary Rodham Clinton
FROM: Jennifer Klein
DATE: 6/28/95
RE: HIV Testing of Pregnant Women and Newborns

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Raymond C. Schappach
Executive Director

cc: Representative John D. Dingell
Commerce Committee Members

TO: Hillary Rodham Clinton
FROM: Jennifer Klein
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

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.

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
Gwendolyn B. Scott, MD, Chairperson
Donna T. Beck, MD
Alan R. Fleischman, MD
Lynne M. Mofenson, MD
Robert H. Pantell, MD
S. Kenneth Schonberg, MD
Martin W. Sklaire, MD
Catherine Wilfert, MD

LIAISON REPRESENTATIVE
Martha F. Rogers, MD,
Centers for Disease Control & Prevention

CONSULTANT
James R. Allen, MD, MPH,
American Medical Association

REFERENCES

1. Connor EM, Sperling RS, Gelber R, et al. Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. *N Engl J Med*. 1994;331:1173–1180
2. Centers for Disease Control. Update: acquired immunodeficiency syndrome—United States, 1992. *MMWR*. 1993;42:547–551,557
3. Ellerbrock TV, Bush TJ, Chamberland ME, Oxtoby MJ. Epidemiology of women with AIDS in the United States, 1981 through 1990. *JAMA*. 1991;265:2971–2975
4. Centers for Disease Control. Characteristics of and HIV infection among women served by publicly funded HIV counseling and testing services—United States, 1989–1990. *MMWR*. 1991;40:195–197,203–204
5. Pratt RD, Hatch R, Dankner WM, Spector SA. Pediatric human immunodeficiency virus infection in a low seroprevalence area. *Pediatr Infect Dis J*. 1993;12:304–310

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.

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

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.

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

There is a need for responsible behavior in Moscow. Instead of undermining each other, Mr. Yeltsin and the Parliament should be working together to create an effective government, a stable ruble and a civil society where public safety is assured without sacrificing civil liberties. Instead of skirmishing over the war in Chechnya, they should be cooperating to end a misadventure that has cost

Special request for TIA

Friday, June 9, 1995

Cumulative AIDS Cases for Women

CDC AIDS Surveillance Data as of December 31, 1994

"A" STATE OF RESIDENCE AT AIDS DX

ST	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Alaska	25	0.0	25	0.0
Alabama	379	0.6	407	0.7
Arkansas	196	0.3	603	1.0
Arizona	243	0.4	846	1.5
California	4241	7.3	5087	8.7
Colorado	239	0.4	5326	9.1
Connecticut	1267	2.1	6573	11.3
Washington, D.C.	859	1.5	7432	12.7
Delaware	217	0.4	7649	13.1
Florida	7837	13.4	15486	26.6
Georgia	1443	2.5	16929	29.0
Hawaii	70	0.1	16999	29.1
Iowa	61	0.1	17060	29.2
Idaho	24	0.0	17084	29.3
Illinois	1542	2.6	18626	31.9
Indiana	252	0.4	18878	32.4
Kansas	98	0.2	18976	32.5
Kentucky	152	0.3	19128	32.8
Louisiana	644	1.1	19772	33.9
Massachusetts	1501	2.6	21273	36.5
Maryland	1993	3.4	23266	39.9
Maine	47	0.1	23313	40.0
Michigan	797	1.4	24110	41.3
Minnesota	146	0.3	24256	41.6
Missouri	347	0.6	24603	42.2
Mississippi	264	0.5	24867	42.6
Montana	19	0.0	24886	42.7
North Carolina	823	1.4	25709	44.0
North Dakota	6	0.0	25715	44.0
Nebraska	49	0.1	25764	44.1
New Hampshire	38	0.1	25802	44.2
New Jersey	6128	10.5	31930	54.7
New Mexico	97	0.1	31986	54.8
Nevada	190	0.3	32177	55.2
New York	15943	27.3	48118	82.5
Ohio	338	0.9	48456	83.4
Oklahoma	165	0.3	48621	83.7
Oregon	156	0.3	48777	84.0
Pennsylvania	1631	2.8	50408	86.8
Rhode Island	245	0.4	50653	87.2
Puerto Rico	2720	4.7	53373	91.8
South Carolina	767	1.3	54140	93.2
South Dakota	7	0.0	54147	93.2
Tennessee	357	0.6	54504	93.8
Texas	2821	3.8	56985	97.6
Utah	82	0.1	57067	97.7
Virginia	721	1.2	57728	99.8
Vermont	26	0.0	57754	99.0
Washington	296	0.5	58050	99.5
Wisconsin	208	0.4	58258	99.9
West Virginia	58	0.1	58316	100.0
Wyoming	11	0.0	58327	100.0

NOTE: Total cumulative AIDS cases reported among women thru 12/31/94 = 58,428. The list above does not include the smaller territories and cases which have residence of report missing.

MEMORANDUM

To: Jennifer Klein

From: Karen Guss

Date: June 14, 1995

Re: HIV testing of newborns and pregnant women "tough issues"

The basic issue: a physician/patient relationship of trust

Effective prevention of HIV transmission and HIV treatment requires a great deal of interaction between patients and health care providers and a serious commitment from the patient: for example, stopping risky behaviors, taking multiple tests (women and newborns), taking AZT several times a day (women and newborns), PCP prophylaxis, and adherence to a changed immunization schedule. Many public health experts and physicians who treat the populations of women most affected by HIV believe that mandatory testing of women or their newborns will destroy any opportunity for creating this type of ongoing, engaged relationship -- and cause more harm than good by driving them out of the health care system. These experts and physicians recommend that counseling women to learn their HIV status and voluntary testing is the best way to foster good relationships and motivate women to get involved in treatment and prevention.

Others (e.g., Mark Rapoport, Commissioner of Health for Westchester County) disagree that HIV testing would have a negative effect on the course of treatment of HIV positive pregnant women and newborns. The two sides of this debate seem to have very different understandings of how HIV positive women feel and how they would behave.

The CDC study is Tuskegee revisited.

The CDC "epidemiological surveillance" has been crucial to saving lives by telling public health officials where they need to target their resources. For example, the creation of the successful Harlem Hospital program was created after the CDC study revealed that African American women were contracting HIV at a high rate. Blinded surveillance does not foreclose instituting vigorous counselling and voluntary testing programs that can save lives -- but unblinding the study is the equivalent of mandatory HIV testing of post-natal women and runs the risks discussed above.

We preform other tests for diseases on pregnant women and newborns as a matter of course.

Yes, but many of these tests, at least in theory, are "routine" and not mandatory, which means that women can choose to opt out of them. In addition, the mandatory tests are a holdover from the days before public health understood the importance of involved, engaged patients. Diseases like PKU, for which newborns are tested, are extremely rare and are not concentrated in any particular population, much less one that may perceive mandatory testing as a form of racial or socioeconomic discrimination. In addition, today none of the diseases for which mandatory testing is the norm are invariably fatal or carry the threat of discrimination and stigma that HIV/AIDS does. Accordingly, learning of a positive test result for one of these diseases is not likely to have the devastating -- and counterproductive -- effect that learning of a positive HIV test may have.

What about women who don't get prenatal care?

According to Dr. Hermann Mendez, a member of the New York State AIDS Advisory Council Subcommittee on Newborn HIV Screening, a pediatrician at SUNY-Downstate, and the director of the Brooklyn Pediatric AIDS Network, "prenatal care" is a term of art, and one defined differently by different people to mean a given quantity and quality of contact with the health care system. Dr. Mendez believes that as many as 98 to 99% of pregnant women have some contact with the health care system, and that health care providers must use each contact to get pregnant women into counseling and voluntary testing. Women who still slip between the cracks should receive counseling and the opportunity to get testing for themselves and their newborn when the child is born. If a woman refuses testing for her newborn, her doctor can tell her that because the infant's HIV status is unknown, she would like her to bring the infant in frequently so that the infant's health can be watched. Each of these return visits presents an opportunity to discuss HIV testing. Dr. Mendez claims that he has never dealt with a mother who refused to bring in her infant for follow-up visits and eventually HIV testing and/or PCP prophylaxis.

What about women who refuse to be voluntarily tested?

There is still a chance to reach these women when the newborn arrives (see above). The people I talked to who are opposed to mandatory testing believe that the number of women who would be driven away by mandatory testing overshadows the number of women who would refuse testing for themselves and/or their infants. (I am expecting a study from Dr. Louis Cooper of the American Academy of Pediatrics calculating the number of women who would have to be driven out of prenatal care by mandatory testing to do more harm than good.) Women who refuse testing seem more likely to be those women who are unwilling or unable to follow the 076 or PCP prophylaxis regime in any event.

But women who don't know their HIV status because neither they nor their babies have been tested could unwittingly transmit HIV by breastfeeding.

In reality, the vast majority of women with HIV do not breastfeed because their lives are too chaotic. In addition, HIV test results do not arrive until at least two weeks after the test is performed, so women who plan to breastfeed are already doing so by the time they get the results. Moreover, women suspected of being HIV positive can be advised not to breastfeed until they are tested and found to be HIV negative.

Voluntary, shmoluntary. There are voluntary testing programs in New York that have had dismal results.

It is important to remember that in New York, HIV test counseling emphasizes the reasons not to be tested, and fails to stress the advantages. Much HIV counseling is not done by the physician who is attending to the other aspects of a woman's pregnancy and is likely to take place in a different setting. (There are 24 pages in the New York State Code that dictate how to perform HIV testing.) These features of HIV testing in New York can be very disturbing and discourage testing. Voluntary testing seems to work best when it is embedded in a process of prenatal care that emphasizes attending to other needs as well as to HIV testing, such as in the Harlem Hospital program.

Should voluntary testing be a routine (opt-out) or an opt-in procedure?

That's a difficult question. Some people, like Dr. Cooper, believe that the test should be routine so as not to scare women off with its strangeness. Others, like Dr. Mendez, believe it should be an opt-in procedure. Dr. Mendez believes that in practice, opt-out tests become mandatory because health care providers in effect drop the part of the discussion that constitutes the opportunity to opt out. In addition, he believes that being HIV positive has such a great impact on people's lives that it is psychologically important for them to have taken affirmative steps to find out their HIV status.

People I contacted to discuss this issue:

Dr. Mark Rapoport, Commissioner of Health for Westchester County
914 593 5154

Troilby DeJung (sp?), New York State AIDS Institute
212 613 4364

Alan Brandt, Harvard School of Public Health
617 432 4365
617 495 3532

Dr. Robert Galen, Medpath Laboratories
216 932 1981

Dr. Louis Cooper, American Academy of Pediatrics
212 523 3365

Dr. Janet Mitchell, Harlem Hospital, obstetrician
212 939 4333

Dr. Hermann Mendez, Brooklyn Pediatric AIDS Network, pediatrician
718 270 3825

Mary Appplegate, New York State Board of Health
518 486 6065

Other possible sources of information:

Dr. Keith Krasinski, New York University Medical Center (in favor of mandatory testing of newborns)

Eileen Tynan, New York State AIDS Institute (I spoke to her colleague (above) while Ms. Tynan was on vacation)

Alan Fleishman, Director, Division of Neonatology, Albert Einstein College of Medicine

Paul Cleary, Department of Health Care Policy at Harvard
617 432 0174

Larry Gostin, Georgetown Law School
202 662 9373

Ron Bayer, Columbia School of Public Health (wrote anti-Hentoff op ed)

Michael Lindsay (sp?), Grady Hospital, Atlanta (Harlem Hospital-type program)

Kathy Wilford (sp?), Duke University Hospital (Harlem Hospital-type program)

LEVEL 1 - 1 OF 1 STORY

The Washington Post

May 20, 1995, Saturday, Final Edition

SECTION: OP-ED; Pg. A23

LENGTH: 798 words

HEADLINE: Another 'Tuskegee'?

BYLINE: Nat Hentoff

BODY:

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."

Such presumably liberal organizations as the ACLU, the National Organization for Women and the Gay Men's Health Crisis do indignantly oppose the unblinding of the test as an invasion of the privacy of the mother whose own infection will be revealed if the child's is. Therefore, all privacy is somehow endangered.

Yet, Rep. Gary Ackerman (D-N.Y.) -- with a 100 percent ACLU rating -- introduced a bill, "The Newborn Infant HIV Notification Act," that compels any state requiring infants' HIV tests to disclose the results to the mother. The bill would apply to the anonymous tests that have been funded and conducted in 45 states by the Centers for Disease Control since 1988, for epidemiological reasons.

Ackerman already had 220 co-sponsors -- more than half the House -- and the ideological range is extraordinary. Ardent liberal Pat Schroeder (D-Colo.) is allied with Robert Dornan (R-Calif.) who makes Pat Buchanan sound like a lyrical moderate. Also on board is Nita Lowey (D-N.Y.), a leader of pro-choice issues in the House, and Bill McCollum (R-Fla.) whose ACLU rating has been zero.

As the bill began to gather momentum, Ackerman was visited, he told me, by Dr. David Satcher, head of the CDC, and Patricia Fleming, the White House director of AIDS policy. The visitors wanted Ackerman to abandon his bill. One of their arguments was that if mothers are told they and their children are infected, they will panic and leave the health care system. There is abundant evidence, however, that black and Latina mothers -- who tend to be often, but hardly exclusively, at risk -- care as much about their children as do white mothers and would not remove them from treatment.

Indeed, a recent poll by New York's Hispanic Federation -- an umbrella organization of many Latino groups -- revealed that two-thirds of those polled support mandatory HIV testing and disclosure for everyone, not only infants.

Gary Ackerman refused to withdraw his bill. He told me that the head of the CDC said he might then consider withdrawing the "blind" tests altogether rather than disclose the results.

Earlier, when the conversation was focusing on increasing criticism -- from various quarters -- of the CDC's "blind test," Ackerman felt that the man from the CDC appeared to be most troubled by the analogy between its study and the Tuskegee "experiment."

From 1932 to 1972, some 400 illiterate black men with syphilis were observed -- but not treated -- by Public Health Service physicians as they deteriorated and eventually died, having been told only that they had "bad blood."

The Tuskegee reference entered the HIV-infant test debate through Dr. Arthur Ammann, a distinguished professor of pediatrics at the University of California. In Jim Dwyer's column, Ammann, referring to the CDC's anonymous testing of infants for HIV, said: "The maintenance of anonymous test results at a time when treatment and prevention are readily available will be recorded in history as analogous to the Tuskegee 'experiment.' "

Suddenly, on May 10, the CDC announced it was immediately suspending its HIV testing for newborns throughout the country. Instead it would focus on encouraging women to engage in voluntary HIV-testing during and before pregnancy. (CDC was silent on the fate of the sizable number of women who do not appear for any prenatal treatment or counseling.)

Rep. Ackerman intends to get a majority of Congress to mandate that the CDC resume the tests -- and from now on disclose the results as well as arrange for counseling. Meanwhile, the American Academy of Pediatrics is "shocked and dismayed" at CDC's total abandonment of its epidemiological tracking tests. Those were the first to show the extent of AIDS among women.

The CDC could have continued the tracking, added disclosure of results, and been free of the taint of the Tuskegee "experiment." But instead the politicized CDC has chosen to fold -- extricating itself from accountability.

LANGUAGE: ENGLISH

LOAD-DATE-MDC: May 20, 1995

LEVEL 1 - 2 OF 4 STORIES

The Washington Post

May 26, 1995, Friday, Final Edition

SECTION: OP-ED; Pg. A27

LENGTH: 1313 words

HEADLINE: It's Not 'Tuskegee' Revisited: The false furor over HIV testing and newborn babies.

BYLINE: Ronald Bayer

BODY:

For seven years state health departments across the nation, with support from the federal Centers for Disease Control and Prevention, have conducted epidemiological surveillance of HIV infection in the population by testing blood samples drawn from hospital, clinic and emergency room patients after the samples have been permanently stripped of all personal identifiers.

Those efforts have been crucial to our understanding of the geographic and demographic pattern of HIV infection in the United States and to our understanding of the future course of the AIDS epidemic. Now Congress is about to consider ill-advised legislation to be introduced by Rep. Gary Ackerman (D-N.Y.) that would prohibit the testing of blood samples, drawn from newborns, that have been rendered anonymous. Faced with that legislative effort, the CDC precipitously announced that it would suspend newborn surveillance pending review. In so doing, it has interrupted the efforts of 45 states that have tracked the number of babies being born to HIV-infected mothers.

Rep. Ackerman's proposal would permit only screening that would make possible the notification of the mothers of babies who test positive. Republicans and Democrats, liberals and conservatives have signed on to the Ackerman proposal, demonstrating the appeal of legislation that, on its face, only seeks to protect mothers and their children. The specter of the Tuskegee syphilis study -- the notorious federal experiment that traced the course of syphilis in African American men who were deprived of the knowledge that they had a treatable sexually transmitted disease -- hovers over the debate.

Public health officials, on the other hand, are appalled at the prospect that the Ackerman proposal will be enacted, depriving them of the capacity to obtain knowledge crucial in the struggle against AIDS. They have a right to be concerned. A serious misunderstanding of the public health and ethical issues involved has permitted an unusual alliance to join hands in what may represent a serious blow to the nation's effort to understand and combat AIDS.

If the Ackerman proposal is enacted, or if the CDC does not reverse its decision, babies and their mothers will not necessarily be better off, but the plug will have been pulled on the radar that tracks the progress of HIV infection among childbearing women and their babies.

To understand the controversy, it is necessary to go back to the mid-1980s, when the practice of testing blood samples after they had been stripped of personal identifiers -- so called blinded seroprevalence studies -- was begun.

Soon after the licensure of the HIV antibody test in 1985, officials at the CDC began to plan for large-scale HIV seroprevalence studies because they understood that tracking cases of full-blown AIDS alone could not provide an adequate picture of the epidemic's dimensions. AIDS cases were but the tip of the iceberg: They told us about infections that had occurred up to 10 years earlier.

However, mandatory testing of identifiable individuals was deemed neither ethical nor politically acceptable. Studies that would rely on volunteers were thought to be unrepresentative -- after all, there was no way of knowing whether those who would agree to participate were more or less likely to be infected.

Therefore, the CDC elected to use, as the basis for its studies, blinded seroprevalence studies based on blood samples already drawn for other clinical purposes. Because such samples would be unlinked to individuals, no person could be placed at risk of the kind of stigma and discrimination that surrounded AIDS. No one's privacy would be violated. And thus it was unnecessary to obtain informed consent before testing occurred.

The very process of eliminating identifiers, however, precluded the possibility of notifying persons who were infected. Since there was little that could be done for people with asymptomatic HIV infection, this was thought to pose no problem. Moreover, none of this would prevent people who wanted to be tested from seeking to learn their HIV status in settings that provided confidential results.

The CDC's proposals for HIV surveillance were subject to searching ethical and legal scrutiny. Did they violate the right of privacy? The right of patients to be informed about their medical conditions? The Office for the Protection from Research Risks at the National Institutes of Health found blinded surveillance both ethical and legal. When a task force made up of ethicists, lawyers, civil liberties advocates, gay rights proponents and public health officials met at the Hastings Center -- a bioethics think tank -- to consider the issue, there was not a single objection to such studies. A 1988 review of the issue by a Canadian working group gave its stamp of approval to blinded seroprevalence surveys. So too did the World Health Organization's Global Program on AIDS.

Now that early clinical intervention for people with HIV infection has become the standard of care, howev er, some people have begun to assert that ethical considerations render blinded surveillance unacceptable. Infected individuals need to know their status so that they can commence treatment. This, it is claimed, is especially the case with regard to babies and their mothers. Is it morally defensible to continue studies that by their very nature preclude the possibility of notifying mothers that their babies carry the antibody to HIV -- and which also indicate that the mothers themselves are infected? Don't both baby and mother have a right to that information? Is not the continuation of blinded HIV surveillance studies analogous to the continuation of the Tuskegee study, begun before the advent of penicillin, but which extended for years after the treatment of syphilis became easy and effective?

The answer in each case is no. In the case of Tuskegee, individuals who were known to be afflicted with syphilis were willfully deprived of that knowledge. Indeed, every effort was made to prevent those impoverished African American men from knowing about their situation or about the availability of therapy. The

situation is very different in the case of HIV.

What the enhanced prospects of therapeutic intervention for both babies and their mothers require is not that we abandon critical surveillance studies but rather that we undertake vigorous efforts to encourage voluntary HIV testing. What blinded seroprevalence studies can do is help guide the necessary public health efforts to identify the women and babies in need of care. They can tell us about where we should expend the greatest efforts in developing the capacity to provide voluntary testing and counseling.

Now that it appears that the risk of transmission of HIV from infected pregnant women to their fetuses can be radically reduced by treatment with AZT during pregnancy, such studies can tell us where to focus resources so that women are encouraged to undergo testing before they give birth. Here there is a chance for real HIV prevention.

Most important, it is crucial that we make certain that women and babies who are identified through voluntary testing programs be provided with access to needed clinical and social services.

To compare blinded surveillance for HIV infection to Tuskegee is to threaten the interest of the mothers and babies who could benefit from carefully targeted efforts to identify those in need of care. Clever political slogans about the right of mothers to know about their babies' lethal infections should not serve to justify an attack on studies that have proved so invaluable in the past and that remain crucial today.

The writer is a professor at the Columbia University School of Public Health and author of "Private Acts, Social Consequences: AIDS and the Politics of Public Health."

GRAPHIC: Illustration, margaret scott

LANGUAGE: ENGLISH

LOAD-DATE-MDC: May 26, 1995

June 27, 1994, Monday, Late Edition - Final

SECTION: Section A; Page 16; Column 1; Editorial Desk

LENGTH: 752 words

HEADLINE: AIDS Babies Deserve Testing

BODY:

All those concerned about babies infected with the virus that causes AIDS can be grateful to Michael Dowling, New York's Commissioner of Social Services. He, at least, has had the decency and common sense to guarantee that all AIDS-infected babies in the foster-care system will be identified and cared for.

But what about the larger number of AIDS-infected babies who are not in foster care? Their fate now hinges on the outcome of a legislative battle that pits the health needs of the babies against the privacy rights of the mothers.

The core issue is whether there should be mandatory testing and identification of all newborns so that those infected with the AIDS virus can be treated -- or simply mandatory counseling of all mothers to try to persuade them to allow testing of themselves and their babies.

Each side in this clash claims its approach will be best for the children. But from the evidence available, the likelihood that counseling alone will do the job seems slight. The only sure way to identify these infants is through testing. The state already tests all newborns, anonymously, to track the epidemic; it could use or enhance that program to identify the infected infants who need medical monitoring and treatment.

The dispute arises because there is no way to identify an infected newborn without identifying the mother as infected; the babies contract the virus from their mothers in the womb or at birth. Thus a mandatory test of any newborn amounts to a mandatory test of the mother as well, subjecting her to possible discrimination if her disease status becomes known. Under current state law, neither the mother nor her child can be tested without written, informed consent.

Commissioner Dowling avoided this dilemma because his agency has legal responsibility for the babies in its care; in effect, he is their surrogate parent. Thus he provoked no opposition when he pledged recently to require routine testing of all children who enter foster care and appear likely to have been exposed to the virus.

But foster children account for only a minority of the several hundred AIDS-infected babies born in New York State each year. Most of these babies leave the hospital without being tested. They are thus robbed of any chance at early treatment. Nothing is done for them until they come down with symptoms of the fatal illness.

Assemblywoman Nettie Mayersohn, of Queens, and State Senator Guy Velella, of the Bronx, would rectify this neglect by disclosing the state's anonymous test

results to the mothers. That may not go far enough. When individual lives are at stake, the tests must be conducted more rigorously than those now performed for statistical purposes. Still, done properly, such testing could identify virtually every infected baby, and the mothers could then be counseled on the importance of medical follow-up.

But leaders of the key health committees in the Legislature are pushing bills, already approved in the Senate, that only call for mandatory counseling of new and expectant mothers. They argue that this would capture the great majority of infected children -- and that babies would get better care if their mothers cooperated in treatment than if they were frightened away from the medical system because of mandatory testing.

Unfortunately, there is scant evidence that the counseling approach would work. The state already sponsors voluntary counseling programs for pregnant women and new mothers in 24 hospitals in AIDS-impacted areas; they typically fail to identify most of the infected babies. Counseling enthusiasts cite the success of Harlem Hospital; some 90 percent of all infected babies born there in 1993 were identified through counseling and voluntary testing. But even the founder of that program doubts its success could be replicated widely. And why neglect even 10 percent of the babies?

Mandatory counseling could be beneficial during prenatal care when doctors can actually save many babies from infection by treating the expectant mother with AZT. Since no one is seriously recommending that pregnant women be forced to take an AIDS test, counseling the mother-to-be on the benefits of testing is the only feasible approach.

But once a mother has delivered an infected baby, that infant deserves to be identified and given the best possible care. By all means, counsel the mother on the advantages of testing and treatment. But for the baby's sake, test the child whether the mother approves or not.

LANGUAGE: ENGLISH

LOAD-DATE: June 27, 1994

American Academy of Pediatrics

TESTIMONY

OF THE

AMERICAN ACADEMY OF PEDIATRICS

BEFORE THE

HEALTH SUBCOMMITTEE

OF THE

COMMERCE COMMITTEE

U. S. HOUSE OF REPRESENTATIVES

ON

PEDIATRIC HIV TESTING

Presented by:

Louis Z. Cooper, MD

May 11, 1995

Department of Government Liaison
The Homer Building
601 Thirteenth Street, N.W.
Suite 400 North
Washington, D.C. 20005
202-347-8600 / 800-336-5475 / FAX: 202-393-6137

Good afternoon. I am Louis Cooper, MD, Director of Pediatrics at St. Lukes Roosevelt Hospital Center in New York and Professor of Pediatrics at Columbia University. I speak as a member of the Board of Directors for the American Academy of Pediatrics (AAP), an association representing over 49,000 pediatricians dedicated to promoting the health and well-being of infants, children, adolescents and young adults. Thank you for the opportunity to appear before you today to discuss the issue of perinatal HIV testing.

This is a passionate debate that knows no political boundaries. Democrats and Republicans, liberals and conservatives, men and women all find themselves together on different sides of the issue.

The development of our own policy statement was a long and deliberate process. The discussions were sometimes tense, often emotional but always grounded in the principle that the final policy must provide a child the most medically appropriate, ethical treatment available to date. This is not a stagnant policy. It is one that will evolve as the epidemic and treatment evolves and the Academy's policy will reflect the most current medical data available.

This is an extraordinarily complicated debate. It is not an "either/or" issue, which some would like to suggest. There is an effort to categorize the arguments surrounding HIV testing of women and infants as either a "privacy of the mother" issue or one of "protection of the child". The consequences are monumental on both sides.

This debate might better be categorized as an "IF-THEN" scenario. From a scientific point, we know that IF a pregnant woman agrees to prenatal HIV testing and is found seropositive, THEN she can choose to enter a program of treatment for herself and her unborn child. IF she enters into the treatment plan, THEN she will significantly reduce the likelihood of transmitting the HIV virus to her child. IF her child is born with HIV virus, THEN the child can receive treatment to delay the onset of opportunistic diseases like *pneumocystis carinii* pneumonia (PCP).

But this medical sequence does not reveal the complexities of getting a woman and child proper treatment and counseling. The social components of the debate must be understood, as well. It is critical that the epidemic be explored, within both the medical and social context.

BACKGROUND

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. In 1993, 12.6 percent of new AIDS cases were diagnosed in women -- up from 6 percent in 1982. (1,2) 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. More than 95 percent of AIDS cases

in children from birth to 4 years old are caused by perinatal infection.

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. (3)

AAP POLICY ON PERINATAL IMMUNODEFICIENCY VIRUS (HIV) TESTING

On the basis of recent advances in the 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."** A copy of the full AAP policy statement is attached.

It is critical to examine the Academy's policy statement in depth in order to understand how the science and societal issues merge in this position.

Routing Testing: Testing needs to be viewed as standard of care for ALL pregnant women in the United States, not just for those in targeted geographic, socio-economic or ethnic groups. The vast majority of physicians in the United States target testing only to women they feel are "at risk" or the woman is required to request the test from the provider, thereby having to identify herself as being someone who has engaged in behaviors that society may not condone (which many people may be reluctant to do). As a result, HIV testing has not been routinely offered and recommended to ALL patients.

Testing programs for HIV antibody must be confidential, voluntary, and accompanied by cultural and ethnically appropriate information regarding HIV infection. The purpose of testing is not to label a mother or infant as infected but to engage the mother into appropriate medical care for herself and her infant. This is the most likely to occur when the woman feels she has been able to make an informed decision about her own health, including HIV testing.

HIV is a chronic illness that requires long-term adherence to often multiple therapies for the mother and child. While testing without patient knowledge or consent appears easier for the health care provider, it would seem less likely to result in a patient that will understand and adhere to chronic therapies for herself and her child.

The ACTG 076 zidovudine (AZT) regime is complex. It requires taking AZT five times daily in the mother and administration four times daily for six weeks to the newborn infant. Adherence to this regimen requires a patient who understands and is motivated to comply with therapy. This is most likely to occur in the context of a trusting provider-patient relationship, and appears unlikely to be facilitated by involuntary testing of a patient without their knowledge.

High test acceptance levels (in the range of 94-97 percent) have been achieved without mandatory testing in places that have initiated routine, universal voluntary testing programs. Jackson Memorial Hospital in Miami, Florida reported in the first three months of 1995 that 96 percent of women counselled prenatally for HIV also agreed to testing. This was up from 92 percent in 1994 (4). Similar rates of acceptance were reported at Grady Memorial Hospital in Atlanta, Georgia; and Harlem Hospital in New York (5).

Routine HIV Education: 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. 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.

Routine HIV education accompanied by offering HIV testing to all pregnant women appears most likely to achieve the goal of engaging a mother in compliance with medical care for herself and infant.

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. It is possible if the benefits of HIV testing are not made known to pregnant women, fear of the potential negative consequence may deter some women from seeking prenatal care. 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.

Documented Testing With Consent: Because the results of ACTG 076 indicate that AZT reduces perinatal transmission of HIV, there is now a compelling reason for universal antepartum HIV education and routine testing with consent.

Documented consent for maternal and/or newborn HIV testing may be obtained in a variety of ways including, but not limited to:

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. The Academy supports utilization of consent procedures that facilitate rapid incorporation of HIV education and testing into the routine medical care

setting. 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.

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 educations accompanied by a signature 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.

TESTING NEWBORNS

Testing of a newborn is too late. The only true "life-saving" treatment is to prevent HIV infection of the infant in the first place. The risk of perinatal HIV transmission can be reduced through the administration of AZT to HIV-infected women and their infants. If we want to attempt to prevent transmission by offering a mother AZT, one must know maternal infection status and start treatment by mid-pregnancy. In times of limited dollars, resources should be used to fund expanded prenatal HIV testing programs, not involuntary newborn testing.

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.

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 forwarded to the mother and, with her consent, to her health care provider. The mother should receive appropriate referral to adult HIV-related services.

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. 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 for the infant.

CONCLUSION:

As noted, 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, the availability of treatment capable of significantly reducing perinatal transmission of HIV provides compelling rationale and motivation for all pregnant women to know their HIV serostatus during early pregnancy.

Voluntary testing for HIV in pregnant women has been proven successful in numerous instances. The Academy urges Congress to avoid well-intentioned efforts to intercede by imposing federal restrictions and requirements on individuals -- whether they are adults or infants.

We specifically oppose legislative efforts such as HR 1289, The Newborn Infant HIV Notification Act. This bill would not reduce perinatal HIV infection in newborns but would result in placing crippling constraints on the efforts of the Centers for Disease Control and Prevention to obtain essential information related to the HIV/AIDS epidemic in the United States.

The CDC-sponsored "HIV Survey in Childbearing Women" seroprevalence study is a critical ingredient in the fight against HIV/AIDS for multiple reasons. It is the best tool we have for tracking the epidemic across the nation. It serves as the critical "Gold-standard" by which we must judge our programs of early detection and early treatment in pregnancy. Equally important, it is the most reliable means of monitoring the effectiveness of programs for reducing transmission of HIV infection in infants and for the early care for those who are infected.

With adequate public health surveillance we may reach conclusions and shape our policies based, not on speculation but on information which is both national and highly focused and local in scope.

We urge Congress to encourage federal agencies to partner with private professional organizations such as the American Academy of Pediatrics to expand on the existing successes of voluntary testing with consent and to promote comprehensive HIV education and voluntary testing of all women as a means to accomplish identification of infants at risk for transmission of the HIV virus. It must be stated that this goal can not be accomplished unless education and testing is coupled with support for programs which assure access to appropriate health services for HIV-infected children and their families.

The Academy stands ready to evaluate its policy on Perinatal HIV Testing on an on-going basis. The rapidly evolving research on HIV/AIDS provides us increased means of controlling the epidemic. We are equally eager to insure our membership understands its responsibility in educating parents and protecting children. Clearly, as further data becomes available, Congress must continue to monitor and evaluate efforts to ensure the needs of these

populations are being met.

Thank you for the opportunity to share the Academy's policy with the Committee. I would be pleased to answer any questions.

1. Centers for Disease Control. Update: acquired immunodeficiency syndrome -- United States, 1992. *MMWR*. 1993;42:547-551,557

2. Ellerbrock TV, Bush TJ, Chamberland ME, Oxtoby MJ. Epidemiology of women with AIDS in the United States, 1981 through 1990. *JAMA*. 1991;265:2971-2975

3. Hsu HW, Moye J Jr, Kunches L, et al. Perinatally acquired human immunodeficiency virus infection; extent of clinical recognition in a population-based cohort. Massachusetts Pediatric HIV Surveillance Working Group. *Pediatr Infect Dis J.* 1992;11:941-945

4. O'Sullivan, Jackson Memorial Hospital, Miami. 1994, 1995

5. Lindsay MK, et al. Routine antepartum human immunodeficiency virus infection screening in an inner-city population; *Obstetrics and Gynecology*. 1989;74:289-294

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention (CDC)
Atlanta GA 30333

MAY 30 1995

Mr. Vincent Carroll
Editorial Page Editor
Denver Rocky Mountain News
400 W. Colfax Avenue
Denver, Colorado 80204-2694

Dear Mr. Carroll:

Recently, some people have proposed mandatory testing of every baby born in the United States for HIV, the virus that causes AIDS. On the surface, this might seem like a good idea. If all newborns were tested, parents or guardians could seek needed medical care.

But testing newborn babies is too little too late to prevent HIV infection and save babies' lives. Last year, a significant study showed HIV-infected women could reduce the risk of transmitting the virus to their babies by taking the drug AZT during pregnancy, labor and delivery, and by giving the baby AZT for the first six weeks after birth. For the first time--and the only time we know of so far--we can prevent HIV infection with a drug.

To take advantage of this preventive treatment, women need to know they're HIV-infected well before giving birth. Far too many don't know, and far too many go through pregnancy without having the opportunity to be tested.

That's why guidelines from the Centers for Disease Control and Prevention (CDC) recommend routine counseling and voluntary HIV testing for all pregnant women, as well as providing treatment before, during, and after birth. If a woman hasn't been tested during pregnancy, CDC recommends offering an HIV test for her baby shortly after delivery and before they leave the hospital.

This individual prevention strategy is being confused with one of the national surveillance tools CDC used to monitor the HIV epidemic. This surveillance tool, the Survey of Childbearing Women, has provided the clearest picture of the threat HIV poses to women and children.

This is how the survey worked: Newborns' blood samples were sent to State laboratories for routine metabolic tests. After those tests were completed and the samples were no longer linked to individual patients, some samples were tested for HIV, often weeks or months after mother and child left the hospital. The samples were not and could never be individual patient diagnostic tools. No one had the names of those who tested positive. But

the survey provided data that enabled State health departments and CDC to predict trends in HIV infection among women and children and helped direct prevention and research efforts.

With recent advances in the ability to decrease perinatal transmission, CDC is now re-evaluating how best to combine prevention and surveillance strategies to meet these important new challenges. Assistant Secretary for Health Dr. Phil Lee asked all State and territorial health departments to suspend the Survey of Childbearing Women until those strategies are developed.

CDC has the responsibility to save lives and prevent disease. We also have the responsibility to direct finite resources and public health efforts where they can do the most good. The best way to accomplish those goals is to fully implement and evaluate the CDC guidelines for routine counseling and voluntary HIV testing during pregnancy and by continuing to monitor HIV and AIDS trends to ensure that prevention efforts are working.

Sincerely,

David Satcher, M.D., Ph.D.
Director

Mandatory Newborn Screening for HIV

Long Overdue, but Not Nearly Enough

Mark S. Rapoport, MD, MPH; Westchester County, N.Y.

Key words: Human immunodeficiency virus (HIV) • Transmission, HIV

The very fact that New York State and New York City have been actively grappling for more than a year with the question of mandatory HIV antibody screening of all newborns tells a great deal: Multiple benefits accrue from knowing that a baby is HIV-seropositive (with actual infection easily verifiable). These include better diagnosis of febrile and pulmonary illness; antibiotic prophylaxis for pneumocystis infection and modified immunization for the baby; counseling on the risks of breast feeding and a host of other medical interventions for the mother; potential location of other cases, especially the child's father; education for prevention of additional transmission by any and all recognized routes; and a broad range of social services (especially those available via the Ryan White Care Act) for the family. None of these benefits are disputed.

For most people, in New York State and elsewhere, the case for screening is straightforward and compelling. It serves the HIV-seropositive baby's health for the data to be known, and parents should want to do well by their children. Parents should have this information, even if they do not want it. The headline on the cover of the Feb-

Dr. Rapoport is commissioner of health, Westchester County, N.Y.

ruary 21, 1994, issue of *New York* magazine may have captured that feeling. It said, "Should It Be a Crime to Treat This Baby for AIDS? The Rising Storm Over the Law That Keeps HIV-Positive Newborns from Early Treatment."

The view of the majority of people most deeply involved in AIDS policy and AIDS care, however, is very different. While they agree that real benefits accrue to both baby and mother and from knowing a baby's serostatus, other considerations take precedence. First, "coercion" is the key issue, with analogy sometimes made to testing Federal prisoners. Second, decade-old fears arise of losing insurance, spouses, and jobs (although the testing would be strictly confidential). Third, there is the unsubstantiated fear that state-mandated testing would forever estrange HIV-seropositive women from their doctors and "the system," and "drive them underground."

I find none of these arguments convincing. The evidence for these fears being realized is very weak. Furthermore, all the perceived difficulties can be minimized by good counseling, good follow-up, and strong safeguards on confidentiality. All of these things are possible and are already being done to a substantial degree. The record of the public health enterprise in maintaining confidentiality is especially good.

A strong sense of the history of discrimination (against women, people of color, and gay men) underlies many of these fears. These sensibilities may be acknowledged, but should not be considered an eternal bar to progress in the ways we combat the plague of AIDS. AIDS is in many ways different from tuberculosis, hepatitis, and syphilis, but it is also similar in many ways. All have some stigma associated with them, nonetheless we have mounted credible efforts against them. In the course of these efforts, we often encounter suspicion, distrust, and fears, but usually we can overcome them. This has direct relevance to the arguments relating to undermining the trust of women who are indirectly tested by a newborn screening program. I think we give these women too little credit if we assume that they will be unable to see the benefits of screening (in retrospect, if not prospectively) and that this failure on their part will translate to a distrust of and unwillingness to coöperate with their doctors, nurses, and social workers. The law would emanate from the state government, not the professional at the bedside, and this distinction is not difficult to discern. Mandating testing programs for hepatitis B and syphilis has not had the feared effects and I do not believe that an HIV newborn-screening program would either. From our efforts with these diseases, we should learn to improve our strategies and to bring AIDS care and AIDS policies closer to the norm for public health problems. Mandatory newborn screening is one such step and is long overdue.

Having said that, we must address the ACTG 076 study showing the clear benefit of giving zidovudine prenatally and intrapartum to pregnant women, and then to the newborn. The beneficial results are truly exciting. Taken together, the 3 interventions cut the rate of vertical transmission by about two-thirds, from 26% to 8%. If all HIV-infected women received the entire "package," perhaps 400 lives would be saved annually in New York State alone. There is a consensus that our emphasis now must be to identify and treat infection in pregnant women at the earliest possible time. Further, there is widespread agreement that a voluntary program would be the best first effort. I concur with this, since in the prenatal context, we confront the likelihood that substantial numbers of women (especially those with the most risk-laden medical history and social circumstances) might be deterred from seeking early prenatal care, or might be more likely to drop out of care. However, I believe that such a program would have to be well designed and continually evaluated, with a mandatory prenatal testing program as a true alternative if a voluntary program did not achieve and maintain high rates of participation.

Although a prenatal effort at testing and treatment must be the first priority, the issue of testing newborns is by no means moot. Some women will not seek prenatal care, and women at highest risk for HIV infection are likely to be over-represented in that group. Also, some women will refuse prenatal testing. What should our response be to the needs of these women and their newborns? I believe that although the absolute number of infected babies will be lower (hopefully, a great deal lower) than under present circumstances, society's obligation to those babies remains unchanged. It is not difficult, I think, to make a case for considering the refusal to accept testing, and the attendant inability to act on the results of that testing, a form of the true "medical neglect."

As a society, we do not tolerate medical neglect of children's needs in regard to conditions other than AIDS, many of which are not nearly as lethal. We certainly need to develop a voluntary prenatal HIV program, incorporating mandatory counseling and minimizing barriers to participation; a mandatory testing program for the already-born child would not be at odds with such a program. In fact, it would reinforce it, just as it would reinforce our commitment to valuing the life of every child, and preserving and caring for those lives in the best way we know how. □

Mandatory Newborn Screening for HIV

The Wrong Answer to the Wrong Question

Alan R. Fleischman, MD; Albert Einstein College of Medicine, Bronx, N.Y. (1995) 212-987-7281

Key words: Human immunodeficiency virus (HIV) • Transmission, HIV

Pediatricians responsible for the care of children infected with the human immunodeficiency virus (HIV) increasingly voice concern that the earliest indication of HIV disease in a child is a fatal infection during the first months of life. Some of these health professionals believe that early identification of children at risk for HIV infection and the initiation of prophylactic therapies will greatly enhance the quality and quantity of children's lives. This has resulted in the recommendation that the standard newborn screening test done on all babies right after birth, which currently identifies several genetic and metabolic disorders, be utilized to find children who are infected with HIV. At first glance this recommendation seems both well-meaning and reasonable, in that the goal of protecting children from unnecessary illness is certainly laudable. However, there are many questions to be raised about the basic assumptions upon which this recommendation is made, as well as serious concerns about the consequences of universal, nonconsensual screening of newborns for HIV.

Ironically, this debate is occurring at a time when exciting new data are emerging about the prevention of transmission of HIV from pregnant women to their fetuses through the administration of zidovudine (ZDV) to the woman during pregnancy and intrapartum, and to the newborn for 6 weeks after birth. The possibility of pharmacologic primary prevention of HIV transmission during pregnancy creates a far more important question: How can we educate the entire population about the importance of knowing their HIV status in order to reduce HIV transmission from one person to another? With particular emphasis on women, how can we create a general standard of medical practice so that every woman who is of reproductive age or is at her first prenatal visit is counseled concerning the benefits of knowing her HIV status and offered appropriate comprehensive services for herself and her family?

A program of counseling and voluntary testing before or early in pregnancy can result in the identification of women who would be offered the option of antiretroviral treatment in an attempt to block HIV transmission to the fetus. Even though all of the questions concerning the use of ZDV in pregnancy have not been answered, the compelling nature of the data demands that we make this option available to women who want this intervention.

It is critically important that the testing of women be done with their permission and full understanding of the benefits and risks of the test. The health care establishment must foster an atmosphere of trust between patients and their providers that can be translated into the delivery of comprehensive services over a long period of time. The treatment of HIV disease and the potential prevention of transmission requires the full cooperation of a knowledgeable and committed patient. Mandatory programs based on coercion will only lead to greater distrust

Clinical Controversies
This exchange of opinions on the mandatory screening of newborns for HIV antibodies is the first in an occasional series of clinical controversies in HIV/AIDS care.

Dr. Fleischman is senior vice president at the New York Academy of Medicine and clinical professor of pediatrics, epidemiology, and social medicine at Albert Einstein College of Medicine, Bronx, N.Y.

and result in patients who are appropriately reluctant to favorably consider therapeutic options presented by well-meaning health care professionals.

Knowing and accepting all of this, some legislators and health care leaders continue to press for mandatory screening of newborns for HIV. They argue that there is a need for a "safety net" to identify newborns whose mothers have not received prenatal care or who have refused to be tested. Of course, they realize that only a small proportion of the babies who test positive for antibody at birth actually will be infected (15% to 30%) while 100% of these infants' mothers will be infected. They also must be aware that the goal of a screening program is not merely the identification and labeling of a potential patient, but also the provision of needed services to that patient and family.

It is incredible to me that some physicians and politicians would consider a program that would combine voluntary testing during the prenatal period and mandatory testing after birth. Can we, as professionals, in good faith counsel women about the importance of knowing their HIV status during pregnancy and accept their voluntary decision about testing, only to test them involuntarily after birth? This seems duplicitous and inappropriate. Of course, all women who have not been tested previously should be counseled at the time of birth about the importance of testing, and we should encourage as many mothers as possible to know their and their newborns' HIV status.

We have the potential to ask the right question and create the right answer. The right question is: How can we offer appropriate counseling to all women and engage them voluntarily to learn their HIV status? If they are HIV-positive, how do we ensure that they receive needed care for themselves and potential interventions to prevent transmission to their fetus and, finally, that they provide care for their infants? This can only be accomplished through a new standard of medical practice that counsels women on the importance and appropriateness of knowing their HIV status before, during, and after pregnancy. Pregnant women should be counseled about the benefits and potential risks of HIV testing while receiving prenatal care and at the time of delivery. Testing should be linked to services and a positive test should result in referral to a program that provides comprehensive care for families.

Perhaps most critically important in the analysis of this complex problem is the issue of trust and respect among health care professionals, their patients, and the public at large. We need not create an atmosphere of fear and coercion when we have the opportunity to develop a program of screening and care that is both voluntary and comprehensive and will likely benefit the vast majority of those in need. We have available today a potential method to identify virtually all of the infants who are at risk for HIV infection through mandatory counseling and encouraged testing of women. With appropriate resources given to education and health care delivery, the desired goal of early identification and treatment of HIV-infected infants can be accomplished without mandatory newborn screening. The right question is how to develop a trusting relationship in order to provide services to those in need. The right answer is universal counseling and voluntary testing.

M E M O R A N D U M

TO: Jennifer Klein

FROM: Zoë Neuberger ZN

DATE: June 13, 1995

RE: HIV Testing of Infants

You will find attached two pieces of information related to the transcript of the Charlie Rose program on HIV testing of infants.

1) An article published in the *New England Journal of Medicine* reporting the results of a study on PCP pneumonia prevention in HIV positive infants. The study was conducted the CDC's PCP Pneumonia Prophylaxis Evaluation Working Group.

2) An article that appeared in *Newsday*, which refers to the lawsuit brought by the Association to Benefit Children, a NYC-based child advocacy group, against Governor Pataki to force the state to release test results. The librarian located 24 other articles on the issue of mandatory HIV testing of infants, but none of the titles suggest that they would discuss the lawsuit. The law library has no information on the case, since it is still pending. If you would like further information, I could call the Association to Benefit Children directly, but I will await your instructions.

cc: Karen Guss

Michelle --

SPECIAL ARTICLE

PROPHYLAXIS AGAINST *PNEUMOCYSTIS CARINII* PNEUMONIA AMONG CHILDREN WITH PERINATALLY ACQUIRED HUMAN IMMUNODEFICIENCY VIRUS INFECTION IN THE UNITED STATES

R.J. SIMONDS, M.D., MARY LOU LINDEGREN, M.D., POLLY THOMAS, M.D., DEBRA HANSON, M.S., BLAKE CALDWELL, M.D., GWENDOLYN SCOTT, M.D., AND MARTHA ROGERS, M.D., FOR THE *PNEUMOCYSTIS CARINII* PNEUMONIA PROPHYLAXIS EVALUATION WORKING GROUP*

Abstract *Background.* *Pneumocystis carinii* pneumonia (PCP) remains a common and often fatal opportunistic infection among children infected with the human immunodeficiency virus (HIV). HIV-infected infants between three and six months of age are particularly vulnerable. Current guidelines recommend prophylaxis in children from birth to 11 months old who have CD4+ counts below 1500 cells per cubic millimeter.

Methods. We used national surveillance data to estimate the annual incidence of PCP among children less than one year old. We reviewed the medical records of 300 children given a diagnosis of PCP between January 1991 and June 1993 to determine why treatment according to the 1991 guidelines for prophylaxis against PCP either was not given or failed to prevent the disease.

Results. In our study the incidence of PCP in the first year of life among infants born to HIV-infected mothers changed little between 1989 and 1992. Among 7080 children born to HIV-infected mothers in 1992, PCP developed in 2.4 percent. Of 300 children with PCP diagnosed from January 1991 through June 1993, 199 (66 percent) had never received prophylaxis, and for 118 of those children (59 percent) exposure to HIV was first identified 30 days or less before the diagnosis of PCP. Among 129 children less than one year old, the CD4+ count declined by an estimated 967 cells per cubic millimeter (95 percent confidence interval, 724 to 1210 cells per cubic millimeter) during the three months before the diagnosis of PCP. Among infants in whom CD4+ counts were determined within one month of the diagnosis of PCP, 18 percent (20 of 110) had at least 1500 cells per cubic millimeter, a level higher than the currently recommended threshold for prophylaxis.

Conclusions. In the United States the incidence of PCP among HIV-infected infants has not declined. If this infection is to be prevented, infants exposed to HIV must be identified earlier, and prophylaxis must be offered to more children than the guidelines currently recommend. (N Engl J Med 1995;332:786-90.)

MOST cases of *Pneumocystis carinii* pneumonia (PCP) in children infected perinatally with the human immunodeficiency virus (HIV) occur in infants between three and six months of age.[1] Because PCP is the most common opportunistic infection classified as indicating the presence of the acquired immunodeficiency syndrome (AIDS) in children,[1] because it is often rapidly fatal,[2] and because it can be prevented by chemoprophylaxis,[3] clinicians and public health officials emphasize its prevention as part of the care of children exposed to HIV and in setting priorities for public health policy. In 1991, a panel of experts in pediatric HIV infection issued guidelines that recommended evaluating the risk of PCP in children born to HIV-infected mothers by measuring the CD4+ cell count and offering chemoprophylaxis if the count is lower than an established age-specific threshold.[4] The thresholds for prophylaxis were as follows: for children from birth through 11 months old, a CD4+ count below 1500 cells per cubic millimeter; 12 through 23 months old, below 750 cells per cubic millimeter; 2 through 5 years old, below 500 cells per cubic millimeter; and 6 through 12 years old, below 200 cells per cubic millimeter.[4]

From the Division of HIV/AIDS, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Atlanta (R.J.S., M.L.L., D.H., B.C., M.R.); the New York City Department of Health, New York (P.T.); and the Department of Pediatrics, University of Miami School of Medicine, Miami (G.S.). Address reprint requests to Dr. Simonds at the Division of HIV/AIDS, Centers for Disease Control and Prevention, 1600 Clifton Rd., Mailstop E-45, Atlanta, GA 30333.

*Other participants in the working group are listed in the Appendix.

Low CD4+ cell counts were thought to identify the HIV-exposed children who were at highest risk for PCP even early in life, when the available techniques were unable to establish a diagnosis of HIV infection.[5,6] Recognizing that PCP occurs most frequently in early infancy, the panel also stressed the need to identify exposure to HIV as soon as possible.

Concern has been aroused about whether the recommended practices can adequately prevent PCP in children born to HIV-infected mothers.[7-9] In one report HIV exposure was often not identified in time for prophylaxis to be given during the peak risk period for PCP in early infancy.[7] Other small studies have suggested that monitoring CD4+ cell counts as recommended in the current guidelines may not be adequate to determine the risk of PCP during the first year of life.[8,9]

To evaluate the 1991 guidelines for prophylaxis, we estimated trends in the incidence of PCP among infants born to HIV-infected mothers between 1989 and 1992. In addition, we conducted a retrospective study of more than half the U.S. children given a diagnosis of PCP in recent years in order to determine how often HIV exposure is identified before PCP is diagnosed, how often the risk of PCP in such children is evaluated by means of CD4+ cell counts, and whether prophylaxis is initiated as recommended in the 1991 guidelines. To determine whether the currently recommended thresholds for prophylaxis and schedules for monitoring are adequate to identify the children at greatest risk for PCP, we also analyzed data on CD4+

cell counts at the time of the diagnosis of PCP and estimated the rate of decline in these counts.

Methods

Estimation of the Incidence of PCP and AIDS in the First Year of Life

We used U.S. surveillance data on AIDS and data from the anonymous U.S. HIV Serosurvey of Childbearing Women to calculate the incidence of PCP and AIDS in the first year of life among children with perinatally acquired HIV infection.

AIDS is a reportable disease throughout the United States. Local health departments collect standardized data on each person reported to have AIDS and transmit these data to the Centers for Disease Control and Prevention (CDC) without personal identifiers. Reporting of AIDS among adults and adolescents is estimated to be over 85 percent complete[14]; no comparable estimate is available for cases among children. For this analysis, we included data on all U.S. children in whom AIDS was diagnosed in the first year of life, whose HIV infection was acquired perinatally, and who were born between 1989 and 1992. We used data reported to the CDC through March 1994 and made adjustments in the number of cases to allow for delays in reporting.[11]

Since 1988, most state health departments have collaborated with the CDC on an anonymous program of testing for antibody to HIV type 1 among women who gave birth; this survey uses residual dried blood specimens collected from newborns for routine metabolic screening.[12] For this analysis, we used the results of tests of specimens collected from all participating states and the District of Columbia (35 jurisdictions in 1989 and 44 in 1992). To estimate the total number of children born each year to women with HIV infection in the United States (excluding Puerto Rico and the territories), we divided the number of children born to HIV-infected women in the survey by the proportion of all U.S. cases of AIDS acquired perinatally that were reported from the participating areas.[12]

We calculated the incidence of PCP in the first year of life by dividing the number of children born in each year and reported to have been given the diagnosis of PCP by one year of age (with adjustment for delays in reporting) by the estimated number of births to HIV-infected women that year. The incidence of AIDS in the first year of life was calculated similarly.

Evaluation of Recent Cases of PCP

From July 1993 through October 1993, we retrospectively reviewed the medical records of children with perinatally acquired HIV infection in whom PCP was diagnosed for the first time between January 1, 1991, and June 30, 1993. We reviewed the records of 300 children with cases of PCP reported through July 1993 from three projects funded by the CDC: a program of population-based AIDS surveillance conducted by health departments in New York City, Florida, and New Jersey (areas with a high incidence of PCP among children), the Pediatric Spectrum of Disease (PSD) project; and the Perinatal AIDS Collaborative Transmission Studies (PACTS).

The PSD project conducts active surveillance for HIV infection in children at seven sites: throughout the state of Massachusetts, throughout Los Angeles County, California, and in selected medical centers in New York City, Washington, D.C., Puerto Rico, Texas, and the San Francisco Bay area.[13] Data are abstracted every six months from the medical records of all the children in each study area known to have been born to HIV-infected mothers.

PACTS is a group of five collaborative, prospective studies of perinatal HIV transmission and of the natural history of HIV infection in children in New York City; Newark, New Jersey; Baltimore; and Atlanta. These studies enroll children of HIV-infected mothers at birth and record laboratory and clinical data on these children prospectively.

For this study, we used a standardized form to collect data from existing data bases and medical records. For each child, we recorded the date of birth, the date of death if the child had died, the date and method of diagnosis of PCP, the date when HIV exposure was first recognized, whether the diagnosis of HIV infection in the child's mother was made before the child's birth, the dates and values for all available CD4+ cell counts, and the starting date and type of prophylaxis against PCP, if it was prescribed. No information was available on the extent of adherence to prescribed prophylactic regimens. We determined whether the child was first evaluated for HIV infection more than 30 days before PCP was diagnosed, because the 1-to-2-month incubation period for PCP[15] suggests that this is the minimal time needed for prophylaxis to be effective.

Statistical Analysis

We used the chi-square statistic with continuity correction to test for differences in proportions between groups. A difference was considered statistically significant if the P value was below 0.05.

To estimate the decline in CD4+ cell counts before the diagnosis of PCP, we used a robust, locally weighted, smoothed regression ("lowess").[15] To assess the variability of this estimated decline during the three months before the diagnosis of PCP, we used a bootstrap technique for regression methods.[16] Two hundred replicates were obtained by sampling with replacement from the residuals of the locally weighted, smoothed regression (the difference between the observed and smoothed values for the CD4+ cell count) and adding the sampled residuals to the smoothed values obtained from the observed data. The regression procedure was repeated for each bootstrap sample. The mean and standard deviation for the decline in CD4+ cell counts during the three months before PCP was diagnosed were computed from these 200 smoothed estimates.

Results

The incidence of PCP in the first year of life among children born to mothers with HIV infection changed little between 1989 and 1992 (Table 1). Assuming a mother-to-child HIV-transmission rate of approximately 20 percent, we estimated the incidence of PCP in the first year of life among HIV-infected children born in 1992 to be approximately 12 percent; this was calculated as 0.024 (the incidence of PCP among children born to HIV-infected mothers) ÷ 0.2 (mother-to-child transmission rate) = 0.12 (the incidence of PCP among HIV-infected children). The overall incidence of AIDS in the first year of life also remained essentially unchanged between 1989 and 1992 (Table 1).

We collected retrospective data on 300 (64 percent) of the 472 U.S. children with perinatally acquired HIV infection who were given a diagnosis of PCP between January 1991 and June 1993 (Fig. 1). This population was made up of 197 (95 percent) of the 207 children with perinatally acquired HIV infection and PCP who were reported through the AIDS-surveillance programs in New York City, Florida, and New Jersey; all 85 children with PCP enrolled in the PSD project (excluding those reported through the AIDS-surveillance program in New York City); and all 18 children with

Table 1. Children Born to HIV-Infected Mothers, Those with PCP Diagnosed in the First Year of Life, and Those with AIDS Diagnosed in the First Year of Life, According to Year of Birth.

Year of Birth	Born to HIV-Infected Mothers*	PCP Diagnosed in First Year of Life†	AIDS Diagnosed in First Year of Life†
	no.	number (percent)	
1989	6400	165 (2.6)	281 (4.4)
1990	6770	193 (2.9)	307 (4.5)
1991	7030	157 (2.2)	329 (4.7)
1992	7080	167 (2.4)	301 (4.3)

*Estimates for the entire United States (excluding Puerto Rico and the territories), based on survey data from 35 states in 1989, 43 in 1990, and 44 in 1991 and 1992.

†Based on AIDS case reports, with adjustment for reporting delays.[11]

PCP who were enrolled in PACTS studies or cared for in medical centers participating in PACTS (excluding those reported through AIDS-surveillance programs in New Jersey and New York City).

The median age of the 300 children at the time of diagnosis of PCP was 5 months (5th and 95th percentiles, 2 and 80 months); 222 children (74 percent) were less than 1 year old. PCP was diagnosed in 130 children in 1991, 121 children in 1992, and 46 children in January through June 1993. PCP was definitively diagnosed (on the basis of examination of histologic or cytologic specimens) in 219 children (73 percent), of whom 174 (79 percent) were less than one year old. A total of 123 (52 percent) of the 236 children for whom such information was available had mothers known to have HIV infection before or at the time of delivery. Of the 300 children, 133 (44 percent) were reported to have died by the time of the study, and 94 (31 percent) died within two months of the diagnosis of PCP. Death was thought to be related to PCP in 89 of the 116 children for whom this information was available (77 percent).

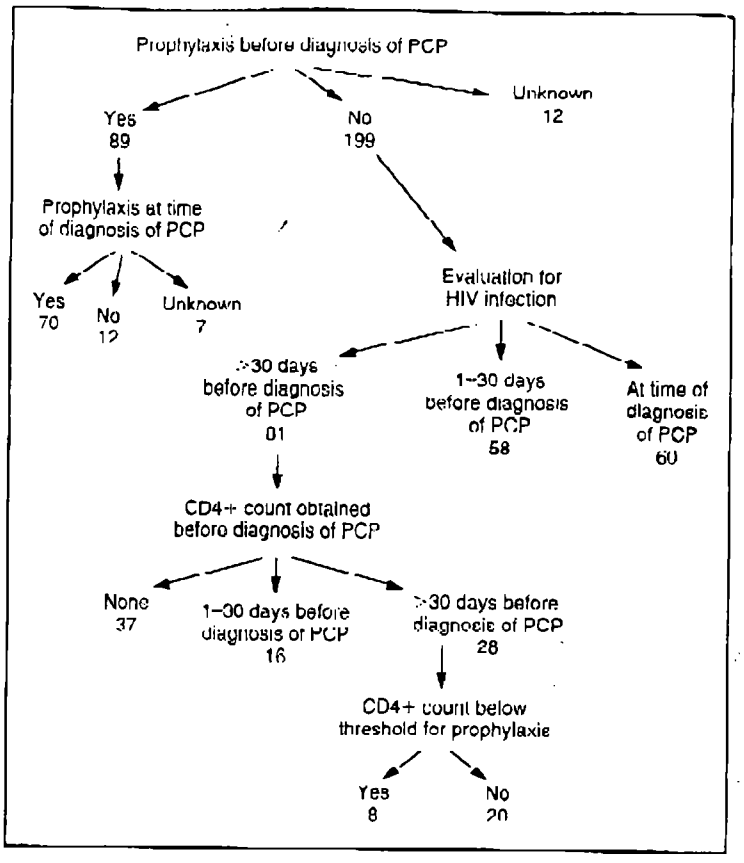

Figure 1. Timing of Prophylaxis among 300 Children with Perinatally Acquired HIV Infection in Whom PCP Was Diagnosed between January 1991 and June 1993.

Of the 300 children, 89 (30 percent) had begun prophylaxis against PCP before PCP was diagnosed, and 199 (66 percent) had not; for 12 children (4 percent) this information was not known (Fig. 1). Children whose mothers were known to be infected with HIV at or before delivery were more likely than other children to receive prophylaxis before PCP was diagnosed (41 percent vs. 21 percent, $P<0.01$). Of the 89 children who had begun prophylaxis before PCP developed, 70 (79 percent) were apparently still receiving prophylaxis against PCP when the disease was diagnosed; however, 14 of those children (20 percent) had been receiving prophylaxis for no more than 30 days before PCP was diagnosed. Prophylaxis at the time of diagnosis consisted of trimethoprim–sulfamethoxazole for 51 children (73 percent), dapsone for 10 (14 percent), aerosolized pentamidine for 6 (9 percent), and intravenous pentamidine for 3 (4 percent).

Of the 199 children who did not receive prophylaxis against PCP before the disease was diagnosed, 60 (30 percent) were first evaluated for HIV infection at the time of diagnosis of PCP, 58 (29 percent) were evaluated 1 to 30 days before the diagnosis of PCP, and 81 (41 percent) more than 30 days before diagnosis (Fig. 1). The proportion of children who were first evaluated for HIV infection no more than 30 days before the diagnosis of PCP was higher among children whose mothers were not known to have HIV infection at or before delivery than among those with mothers who had recognized HIV infection (84 percent vs. 21 percent; relative risk, 4.0; 95 percent confidence interval, 3.0 to 8.0; $P<0.001$); these percentages did not change significantly from 1991 through 1993.

Of the 81 children who did not receive prophylaxis and who were first evaluated for HIV infection more than 30 days before PCP was diagnosed, 53 (65 percent) apparently had no CD4+ cell counts performed at all or none more than 30 days before the diagnosis of PCP. Of the 28 children for whom CD4+ cell counts were available more than 30 days before PCP was diagnosed, 20 (71 percent) had no counts below the recommended threshold for prophylaxis against PCP. Fifteen of these 20 children (75 percent) were less than one year old, and PCP was diagnosed definitively in 15 (75 percent).

Including both children who had been given prophylaxis against PCP and those who had not, 180 children had a total of 378 CD4+ cell counts performed before or at the time of the diagnosis of PCP. The estimated decline in the CD4+ cell count during the three months before the diagnosis of PCP was 967 cells per cubic millimeter (95 percent confidence interval, 724 to 1210 cells) among 129 children less than one year old (Fig. 2) and 15 cells per cubic millimeter (95 percent confidence interval, 0 to 62 cells) among 51 children at least one year old.

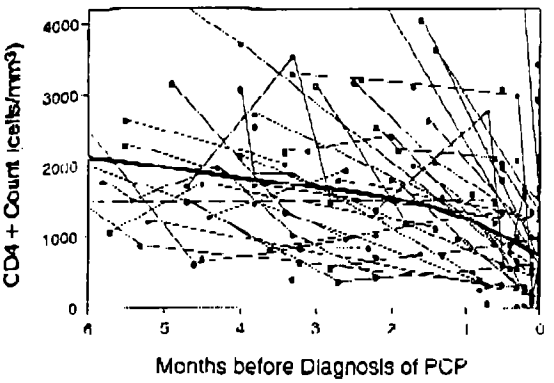

Figure 3. CD4+ Cell Counts during the Six Months before the Diagnosis of PCP in 129 Children <11 Months Old at the Time of Diagnosis.

Points indicate CD4+ cell counts; the thin lines connect measurements in the same child; the thick line represents the locally weighted, smoothed regression curve, and the dashed line represents the current threshold for prophylaxis against PCP in this age group (<1500 cells per cubic millimeter).

For 113 children (47 percent), the CD4+ cell count was measured within one month of the diagnosis of PCP (Table 2). Among the 113 of these children who were less than one year old at the time of diagnosis, the median CD4+ count was 552 cells per cubic millimeter (25th and 75th percentiles, 249 and 1250 cells). Among the 28 children who were at least one year old at diagnosis, the median CD4+ count was 29 cells per cubic millimeter (25th and 75th percentiles, 7 and 461 cells). Twenty of the 113 children less than one year old at the time of diagnosis (18 percent) had CD4+ counts of 1,000 or more cells per cubic millimeter. For 160 children, either the number or the percentage of CD4+ cells was measured within one month of the diagnosis of PCP; 24 of 129 children less than one year old (19 percent) and 7 of 31 children one year old or older (23 percent) did not fall below the recommended threshold for initiating prophylaxis in terms of either CD4+ cell counts or percentage of CD4+ cells (20 percent of total lymphocytes for children of any age).[4]

Discussion

Despite the publication in 1991 of guidelines for prophylaxis against PCP[1] and even with continuing increases in the use of prophylaxis,[7,8] the estimated incidence of PCP in the first year of life among children with perinatally acquired HIV infection in the United States (12 percent) has changed little in recent years and is virtually identical to the rate of 11.8 percent reported among children prospectively followed in the European Collaborative Study, very few of whom had received prophylaxis.[9]

Although limited by our reliance on data collected retrospectively, our evaluation of a large sample of U.S. children with perinatally acquired HIV infection in whom PCP was diagnosed between January 1991 and June 1993 highlights several important factors contributing to the continued substantial incidence of PCP. Most of the children we studied (66 percent) did not receive prophylaxis before PCP was diagnosed. Because many of these cases might have been prevented by prophylaxis, they represent a failure of current strategies for identifying exposure to HIV, evaluating the risk of PCP, and initiating prophylaxis in the children with the highest risk.

The most prominent gap in efforts to prevent PCP in HIV-infected children remains the failure to recognize HIV exposure soon enough to begin prophylaxis before PCP develops. Over half the children in this study who were not given prophylaxis before PCP developed were not recognized as having exposure to HIV in time for prophylaxis to prevent the disease. Moreover, this proportion did not decrease over the 2½ years of the study. Not surprisingly, lack of knowledge of the mother's HIV infection before birth was associated with late recognition of exposure to HIV among the children in this study.

Some young children may not be protected by prophylaxis because the length of time required to obtain a CD4+ cell count in some communities may delay the initiation of therapy until after the period of highest risk for PCP (three to six months of age). In this study, nearly two thirds of children whose exposure to HIV was identified but who were not given prophylaxis had no record of CD4+ cell counts until 30 days or less before the diagnosis of PCP was made. Although some of these children may have had measurements that were not entered in the available medical records, it is likely that for others PCP developed before the CD4+ cell count was determined.

Even among children whose CD4+ cell counts were evaluated as recommended, the established thresholds for prophylaxis may have caused many children at high risk for PCP to be categorized as needing no prophylaxis; this was especially true of those in the first year of life, when the risk of PCP is greatest,[1] for whom the criterion for prophylaxis is a CD4+ count of less than 1500 cells per cubic millimeter. Moreover, because CD4+ cell counts in infants may decline rapidly, the monitoring of counts every three months, as recommended in the 1991 guidelines, may not permit detection of the drop early enough for prophylaxis to be useful. The estimated rate of decline of more than 300 cells per cubic millimeter per month before the diagnosis of PCP in infants less than one year old is much greater than the declines of fewer than 100 cells per cubic millimeter per month reported among HIV-infected

Table 2. CD4+ Cell Counts within One Month of the Diagnosis of PCP, According to Age at Diagnosis.

CD4+ Count (cells/mm³)	Age (mo)			
	0–11	12–23	24–71	≥72
≥1500	20	1	0	0
750–1499	29	1	2	0
500–749	14	1	1	1
200–499	37	0	2	1
<200	23	1	10	7
Total	113	4	15	9

and uninfected infants and older children in other studies[19-22] and among older children in this study.

In some children, PCP may have occurred despite prophylaxis; as many as 23 percent of the children with PCP in this study may have been receiving prophylaxis at the time the disease was diagnosed. However, this figure may overestimate the number of children for whom prophylaxis truly failed, because we do not know whether the children actually received the medication. In addition, without a control group of HIV-infected children in whom PCP did not develop, we cannot assess the efficacy of different regimens for prophylaxis against PCP. Clinical trials have demonstrated the efficacy of prophylaxis against PCP among children with cancer[5] and adults with HIV infection,[23] but none have been conducted among HIV-infected children.

Effective prevention of PCP in children with HIV infection requires that their exposure to HIV be identified and prophylaxis begun before two months of age. The recent demonstration that zidovudine can substantially reduce perinatal transmission of HIV offers a compelling reason for prenatal identification of infection.[24] The diagnosis of HIV infection in a woman during or even before pregnancy allows her to receive medical and other services to preserve her own health, permits interventions such as zidovudine therapy to be prescribed to reduce the risk of HIV infection in her child, and makes possible the early initiation of prophylaxis against PCP for the child. Offering counseling and voluntary testing for HIV to all pregnant women may be the single most important step toward preventing PCP in children. The Public Health Service is currently revising its guidelines for the counseling and voluntary HIV testing of pregnant women.

Data from this study also suggest that the current strategies for prophylaxis may not be effective in preventing PCP in the infants who are at highest risk for the disease. A working group convened by the National Pediatric HIV Resource Center and the CDC has recently developed revised guidelines for prophylaxis against PCP in children that recommend starting prophylaxis for all infants born to HIV-infected mothers, beginning at four to six weeks of life. The guidelines recommend discontinuing prophylaxis in children who are determined not to have HIV infection but continuing it throughout the first year of life for all HIV-infected children.

Appendix

In addition to the authors, the *Pneumocystis carinii* Pneumonia Prophylaxis Evaluation Working Group includes the following: the PSD project (H.-W. Hsu, Massachusetts Department of Health, Boston; L. Mascola, Los Angeles County Department of Health, Los Angeles; K. Shaner, Texas Department of Health, Austin; Y. Maldonado, Stanford University, Palo Alto, Calif.; I. Ortiz, Puerto Rico Department of Health, San Juan; R. Parrott, Washington Children's National Medical Center, Washington, D.C.; and P. Thomas, New York City Department of Health, New York); the CDC PACTS (D. Thea, Medical and Health Research Association, New York; E. Schoenbaum, Montefiore Medical Center, New York; P. Palumbo, University of Medicine and Dentistry of New Jersey, Newark; J. Farley, University of Maryland, Baltimore; and S. Nesheim, Emory University, Atlanta); G. Connolly, Florida Department of Health and Rehabilitative Services, Tallahassee; F. Laraque and J. Beil, New Jersey Department of Health, Trenton; G. McSherry, University of Medicine and Dentistry of New Jersey, Newark; and M. Vazquez, M. Kaluba, S. Davis, J. Karon, and D. Burgess, CDC, Atlanta.

References

1. Simonds RJ, Oxtoby MJ, Caldwell MB, Gwinn ML, Rogers MF. *Pneumocystis carinii* pneumonia among US children with perinatally acquired HIV infection. JAMA 1991;270:470-3.
2. Scott GB, Hutto C, Makuch RW, et al. Survival in children with perinatally acquired human immunodeficiency virus type 1 infection. N Engl J Med 1989;321:1791-6.
3. Hughes WT, Kuhn S, Chaudhary S, et al. Successful chemoprophylaxis for *Pneumocystis carinii* pneumonitis. N Engl J Med 1977;297:1419-26.
4. Guidelines for prophylaxis against *Pneumocystis carinii* pneumonia for children infected with human immunodeficiency virus. MMWR Morb Mortal Wkly Rep 1991;40(RR-2):1-13.
5. Connor E, Bagarazzi M, McSherry G, et al. Clinical and laboratory correlates of *Pneumocystis carinii* pneumonia in children infected with HIV. JAMA 1991;265:1693-7.
6. Kovacs A, Frederick T, Church J, Eller A, Oxtoby M, Mascola L. CD4 T-lymphocyte counts and *Pneumocystis carinii* pneumonia in pediatric HIV infection. JAMA 1991;265:1698-703.
7. Hsu HW, Moye J Jr, Kunches L, et al. Perinatally acquired human immunodeficiency virus infection: extent of clinical recognition in a population-based cohort. Pediatr Infect Dis J 1992;11:941-5.
8. Israele V, Wittek A, Courville T, Srugo I, Brunell P. *Pneumocystis carinii* pneumonia (PCP) in infants with CD4 counts greater than 2000 cells/mm³. In: Abstracts of the Eighth International Conference on AIDS/Third STD World Congress, Amsterdam, July 19–24, 1992. Amsterdam: CONGREX, 1992:II233. abstract.
9. European Collaborative Study Group. CD4 T cell count as predictor of *Pneumocystis carinii* pneumonia in children born to mothers infected with HIV. BMJ 1994;308:437-40.
10. Rosenblum LS, Buehler JW, Morgan MW, et al. The completeness of AIDS case reporting, 1988: a multisite collaborative surveillance project. Am J Public Health 1992;82:1495-9.
11. Karon JM, Buehler JW, Byers RH, et al. Projections of the number of persons diagnosed with AIDS and the number of immunosuppressed HIV-infected persons — United States, 1992–1994. MMWR Morb Mortal Wkly Rep 1992;41(RR-18):1-29.
12. Gwinn M, Pappaioanou M, George JR, et al. Prevalence of HIV infection in childbearing women in the United States: surveillance using newborn blood samples. JAMA 1991;265:1704-8.
13. Caldwell MB, Mascola L, Smith W, et al. Biologic, foster, and adoptive parents: care givers of children exposed perinatally to human immunodeficiency virus in the United States. Pediatrics 1992;90:603-7.
14. Ruebush TK II, Weinstein RA, Buehner RL, et al. An outbreak of Pneumocystis pneumonia in children with acute lymphocytic leukemia. Am J Dis Child 1978;132:143-8.
15. Cleveland WS. Robust locally weighted regression and smoothing scatterplots. J Am Stat Assoc 1979;74:829-36.
16. Efron B, Tibshirani RJ. An introduction to the bootstrap. New York: Chapman & Hall, 1993.
17. Caldwell B, Lancaster J, Thomas P, et al. Children with symptomatic HIV infection: what medications are they receiving? In: Abstracts of the 34th Interscience Conference on Antimicrobial Agents and Chemotherapy, Orlando, Fla., October 4–7, 1994. Washington, D.C.: American Society for Microbiology, 1994:36. abstract.
18. Oleske J, Mofenson L, Lenderking W, et al. PCP prophylaxis (PRO) among children followed in ACTG pediatric long-term protocol 219. Clin Infect Dis 1994;19:611. abstract.
19. The European Collaborative Study. Age-related standards for T lymphocyte subsets based on uninfected children born to human immunodeficiency virus 1-infected women. Pediatr Infect Dis J 1992;11:1018-26.
20. Mofenson LM, Bethel J, Moye J Jr, Flyer P, Nugent R. Effect of intravenous immunoglobulin (IVIG) on CD4+ lymphocyte decline in HIV-infected children in a clinical trial of IVIG infection prophylaxis. J Acquir Immune Defic Syndr 1993;6:1103-13.
21. Denny T, Yogev R, Gelman R, et al. Lymphocyte subsets in healthy children during the first 5 years of life. JAMA 1992;267:1484-8. [Erratum, JAMA 1992;267:3154.]
22. McKinney RE Jr, Wilfert CM. Lymphocyte subsets in children younger than 2 years old: normal values in a population at risk for human immunodeficiency virus infection and diagnostic and prognostic application to infected children. Pediatr Infect Dis J 1992;11:639-44.
23. Fischl MA, Dickinson GM, La Voie L. Safety and efficacy of sulfamethoxazole and trimethoprim chemoprophylaxis for *Pneumocystis carinii* pneumonia in AIDS. JAMA 1988;259:1185-9.
24. Connor EM, Sperling RS, Gelber R, et al. Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. N Engl J Med 1994;331:1173-80.

LEVEL 1 - 1 OF 2 STORIES

Newsday

March 15, 1995, Wednesday, NASSAU AND SUFFOLK EDITION

SECTION: NEWS; Pg. A04

LENGTH: 601 words

HEADLINE: Panel Backs Giving Moms HIV Test Results

BYLINE: By Rebecca Blumenstein. ALBANY BUREAU

DATELINE: Albany

BODY:

Albany - Reigniting one of last year's most controversial legislative issues, a state Senate committee yesterday approved a bill that would require that all mothers be notified of the results of HIV tests on their newborns.

"I want to get this debate going," said Sen. Kemp Hannon (R-Garden City), a chief backer of the bill and the newly appointed chairman of the Senate's Health Committee. The panel passed the measure yesterday.

The bill, vehemently opposed by AIDS activists and some Democratic legislators, would "unblind" the HIV test now conducted anonymously at birth on every newborn in the state to help state health officials track the epidemic. Mothers would be required by law to be notified of the HIV status of their child. For the estimated 1,800 mothers whose babies test positive every year, the disclosure would mean that they, too, have the AIDS virus.

This year, pressure for a major confrontation over the bill already seems to be building. Sponsored by Assemb. Nettie Mayersohn (D-Queens) and Sen. Guy Velella (R-Bronx), the bill attracted the sponsorship of Gov. George Pataki when he was a senator last year. He also supported it during his gubernatorial campaign. And yesterday, a Manhattan-based child advocacy group, filed a lawsuit against Pataki and other state officials to force the state to disclose the results of the tests.

"It is the state's duty to acknowledge this public health crisis and help children and their families with HIV," said Gretchen Buchenholz, executive director of the Association to Benefit Children, which filed the suit in New York State Supreme Court. There is "a public emergency of thousands of children whose illness goes undetected until they come down with debilitating and often fatal opportunistic diseases."

Opponents of the bill contend that mandatory testing would drive pregnant women who don't want to know their HIV status away from the health care they need. Instead, they favor a compromise measure, which the Senate at the last hour failed to act on last year, that would mandate counseling to increase the numbers of women who voluntarily consent to testing themselves or their babies. Opponents say their position has been recently buoyed by scientific research that indicates a woman who receives the drug AZT during pregnancy will reduce the risk of passing the HIV virus onto her child by two-thirds.

"If we can get women who are HIV positive into AZT programs, then we can significantly reduce the passage from mother to child," said Sen. Richard Dollinger (D-Rochester), a member of the Senate's health committee. "I would put the money into prevention and counseling."

Hannon argued more women would receive treatment with the mandatory testing. "We know for sure if they are not notified, 100 percent won't come in," said Hannon. "If you don't have the information you can't act on it."

Sen. Michael Tully (R-Port Washington), who chaired the Senate's health committee before Hannon, said yesterday he was surprised such an emotional issue was being introduced in the middle of budget negotiations. Tully said he remains committed to the compromise bill he supported that mandates counseling instead of testing.

Citing the new medicial evidence about the preventive effect of AZT, the Centers for Disease Control last month released a new recommendation favoring voluntary over mandatory testing of pregnant women and babies.

But advocates of mandatory disclosure claim that more of the medical establishment is coming to their side, including the New York State Association of Public Health Officials.

LANGUAGE: ENGLISH

LOAD-DATE: March 16, 1995

LEVEL 1 - 25 STORIES

attached 1. Newsday, March 15, 1995, Wednesday, CITY EDITION, NEWS; Pg. A19, 481 words, HIV Test of Tots Clears a Hurdle, By Rebecca Blumenstein. ALBANY BUREAU Albany, ACQUIRED IMMUNE DEFICIENCY SYNDROME; TEST; CHILDREN; BIRTH; DISSENT; LEGISLATURE; ISSUE; INFANT; KEMP HANNON; LAW; PROPOSED;;

attached 2. Newsday, March 15, 1995, Wednesday, NASSAU AND SUFFOLK EDITION, NEWS; Pg. A04, 601 words, Panel Backs Giving Moms HIV Test Results, By Rebecca Blumenstein. ALBANY BUREAU, Albany, ACQUIRED IMMUNE DEFICIENCY SYNDROME; TEST; MOTHER; RESULT; NEW YORK STATE; INFANT; KEMP HANNON;

* 3. The New York Times, February 25, 1994, Friday, Late Edition - Final, Section B; Page 4; Column 1; Metropolitan Desk , 910 words, AIDS Panel Urges Tests for More Women, By MIREYA NAVARRO

4. Newsday, January 17, 1989, Tuesday, ALL EDITIONS, DISCOVERY; AIDS; Pg. 5, 1710 words, Testing Drugs on Babies, By Gail McBride. Gail McBride is a free-lance writer.

5. Newsday, August 10, 1994, Wednesday, CITY EDITION, VIEWPOINTS; YOKOHAMA AIDS WATCH; Pg. 30, 410 words, In the Interest Of the Child; Protect newborns from HIV, EDITORIAL; CHILDREN; ACQUIRED IMMUNE DEFICIENCY SYNDROME; HEALTH CARE; HEALTH; INFANT; HIV; TREATMENT; JAPAN; AZT; MEETING

6. Los Angeles Times, February 7, 1995, Tuesday, Home Edition, Life & Style; Part E; Page 1; Column 2; View Desk, 1447 words, WHOSE LIFE IS IT?; WEIGHING THE ETHICS OF KEEPING UNBORN BABIES SAFE FROM HIV, By PAMELA WARRICK, TIMES STAFF WRITER

7. Newsday, January 17, 1995, Tuesday, NASSAU AND SUFFOLK EDITION, HEALTH & DISCOVERY; AIDS PREVENTION; Pg. B23 Other Edition:Brooklyn25 City, 2171 words, Stumbling Block To Progress; Shrinking funding and ethical concerns threaten a major breakthrough in preventing the spread of the AIDS virus between mother and child, By Laurie Garrett. STAFF WRITER, COVER; ACQUIRED IMMUNE DEFICIENCY SYNDROME; MOTHER; INFANT; PREGNANCY; DRUG; AZT; RESEARCH; WORLD; MAP; ETHIC; DANIEL TARANTOLA; QUOTE

8. Newsday, November 9, 1993, Tuesday, CITY EDITION, NEWS; Pg. 22 Other Edition: Nassau and Suffolk Pg. 20, 544 words, Testing Newborns For AIDS Debated By John Riley. ALBANY BUREAU, ACQUIRED IMMUNE DEFICIENCY SYNDROME; TEST; CHILDREN; DEBATE; RIGHTS; NEW YORK STATE; PHYLLIS SHARPE; ELEANOR MITCHELL; PHYSICIANS;

9. Newsday, June 28, 1994, Tuesday, CITY EDITION, VIEWPOINTS; ABOUT AIDS TESTING; Pg. A28, 873 words, Myths Won't Save Babies' Lives, By Debra Cooper. Debra Cooper is a spokesperson for the New York State Task Force on Women and AIDS., OPINION; ACQUIRED IMMUNE DEFICIENCY SYNDROME; TEST; HEALTH; MEDICINE; CHILDREN; TREATMENT; HEALTH CARE; REFORM

* 10. The New York Times, April 5, 1995, Wednesday, Late Edition - Final, Section B; Page 4; Column 1; Metropolitan Desk , 900 words, Senate Votes to Require Telling Mothers of H.I.V. Results, By KEVIN SACK , ALBANY, April 4

11. Chicago Tribune, April 26, 1987 Sunday, FINAL EDITION Correction Appended, SUNDAY MAGAZINE; Pg. 14; ZONE: C, 18907 words, CONFRONTING AIDS BLUNT FACTS ABOUT AN INSIDIOUS KILLER--AND WHAT YOU NEED TO KNOW TO PROTECT YOURSELF., By

LEVEL 1 - 25 STORIES

Dennis L. Breo, special-assignments editor of American Medical News and a SUNDAY contributing editor.

12. The Washington Post, April 9, 1994, Saturday, Final Edition, EDITORIAL; PAGE A21; SWEET LAND OF LIBERTY, 774 words, When a Baby Is HIV Positive, Nat Hentoff

13. Sacramento Bee, April 11, 1994, METRO FINAL, EDITORIALS; Pg. B13, 1200 words, "IT'S A BABY, NOT A STATISTIC', Nat Hentoff

14. The Denver Post, April 6, 1995 Thursday, 2D EDITION, Pg. E-01, 2416 words, HIV tests inconsistent in pregnancies Researchers' findings not applied, Carol Kreck, Denver Post Staff Writer

15. Rocky Mountain News, April 18, 1994, Monday, EDITORIAL; Ed. F; Pg.33A, 800 words, HIV-infected babies sacrificed for sake of mothers' privacy, Nat Hentoff; Newspaper Enterprise Association

16. Newsday, February 3, 1995, Friday, NASSAU AND SUFFOLK EDITION, NEWS; Pg. A56, 689 words, Test May Reduce HIV Infection of Newborns, By Laurie Garrett. STAFF CORRESPONDENT, Washington, ACQUIRED IMMUNE DEFICIENCY SYNDROME; TEST; INFANT; BIRTH; REDUCTION; TREATMENT

17. Time, July 4, 1994, U.S. Edition, MEDICINE; Pg. 60, 1182 words, Moms, Kids and AIDS; Can testing and treatment before and after birth help thousands of youngsters threatened by HIV?, By Christine Gorman; Reported by Sam Allis/New York, with other bureaus

18. Newsday, August 25, 1993, Wednesday, CITY EDITION, NEWS; Pg. 15, 1282 words, FOCUS ON: Mandatory AIDS Tests; Pain of Knowing; Doctor, clinician disagree on testing moms, newborns, By John Riley. ALBANY BUREAU, ACQUIRED IMMUNE DEFICIENCY SYNDROME; TEST; INFANT; MOTHER; NEW YORK CITY

19. The Washington Post, April 08, 1995, Saturday, Final Edition, OP-ED; Pg. A19, 797 words, Privacy That Kills

20. The New York Times, July 3, 1994, Sunday, Late Edition - Final, Section 1; Page 1; Column 3; Metropolitan Desk , 1604 words, A BILL TO REQUIRE H.I.V. COUNSELING BACKED IN ALBANY, By KEVIN SACK, Special to The New York Times , ALBANY, July 2

21. Los Angeles Times, November 14, 1994, Monday, Home Edition, Metro; Part B; Page 6; Column 1; Editorial Writers Desk, 722 words, A GAIN AGAINST AIDS THAT CARRIES ETHICAL QUESTIONS; SHOULD HIV-POSITIVE PREGNANT WOMEN FACE MANDATORY AZT THERAPY?

22. The Washington Post, October 5, 1988, Wednesday, Final Edition, FIRST SECTION; PAGE A1, 1200 words, AZT Tests Seek to Stem Fetal AIDS, Susan Okie, Washington Post Staff Writer, NATIONAL NEWS

23. Newsday, March 31, 1994, Thursday, CITY EDITION, NEWS; Pg. A15, 1262 words FFOUCUS ON: The AIDS Baby Bill; On a Crusade; Lawmaker's profile grows, By Manuel Perez-Rivas. STAFF WRITER, Albany, NETTIE MAYERSOHN; PROFILE; ACQUIRED IMMUNE DEFICIENCY SYNDROME; LAW; PROPOSED; INFANT; TEST

LEVEL 1 - 25 STORIES

24. Newsday, March 17, 1995, Friday, CITY EDITION, VIEWPOINTS; Pg. A36, 372 words, Infants' Rights; Tell mothers their HIV status, EDITORIAL; ACQUIRED IMMUNE DEFICIENCY SYNDROME; HIV; INFANT; MOTHER; BIRTH; TEST; INFORMATION

25. Newsday, October 17, 1989, Tuesday, ALL EDITIONS, DISCOVERY; AIDS; Pg. 5, 1430 words, AZT Treatment for Babies; The drug is toxic, but infants born infected with HIV are likely to develop disease quickly and die., By Laurie Garrett