CDC UPDATE
CENTERS FOR DISEASE CONTROL AND PREVENTION
NCHSTP
February 1997

1996 HIV/AIDS Trends Provide Evidence of Success in HIV Prevention and Treatment

Good News Brings New Challenges

Since 1992, annual increases in AIDS incidence (or the estimated number of people diagnosed with AIDS each year) have slowed to less than 5%. This trend continued in 1996 with an increase of only 2%, reflecting in part the ongoing success of prevention efforts. Additionally, for the first time in the epidemic, there has been a marked decrease in death rates among people with AIDS. The decline in deaths is likely due to both the slowing of the epidemic overall and to improved treatments over the past several years, which have lengthened the lifespan of people with AIDS. While it is too soon to determine the impact protease inhibitors will have on these trends, these drugs promise to further lengthen the lifespan of individuals living with HIV.

As treatment advances continue to improve survival, we will face a number of key challenges:

- First, if the number of new HIV infections each year (HIV incidence) remains stable or increases, and deaths continue to decrease, there will be an increasing number of people living with HIV and AIDS. Additional resources will likely be needed for services, treatment, and care.

- Second, to continue to provide the necessary data to plan, direct, and evaluate HIV prevention efforts, HIV/AIDS surveillance systems must adapt to changes in medical practices which increase survival following diagnosis of HIV or AIDS. If progression to AIDS is successfully delayed for an increasing number of individuals, AIDS case reports may no longer provide a reliable indication of trends in the epidemic and will underrepresent the need for treatment services. Surveillance systems will therefore need to improve methods to monitor the number of individuals with HIV infection.

- And finally, as we continue to work to develop better treatment options, we must not lose sight of the fact that preventing HIV infection reduces the number of people who need to undergo complex, costly treatment regimens. Prevention remains our best and most cost-effective approach for bringing the HIV/AIDS epidemic under control and saving lives.

The 1996 Data: Trends in Case Reports, Estimated AIDS Incidence and Deaths

AIDS Cases Reported through December 1996

- 581,429 people with AIDS have been reported to date
- Of these, 488,300 (84%) were men, 85,500 (15%) were women, and 7,629 (1%) were children.
- In 1996, blacks accounted for a larger proportion of AIDS cases (41%) than whites for the first time.
- The proportion of female AIDS cases continued to increase. In 1996, women accounted for 20% of newly reported AIDS cases.

Trends in AIDS Incidence through 1995:

Between 1994 and 1995, the estimated number of people diagnosed with AIDS (AIDS incidence) increased 2%, from 61,200 to 62,200. These estimates reflect a slowing in the growth of the epidemic, with an average of 15,200 people diagnosed each quarter between January 1994 and June 1996. Hopefully, with a combined strategy to prevent new infections and to provide early diagnosis and treatment for people who are infected, AIDS incidence will soon begin to decline.

During 1995:

- AIDS incidence rates per 100,000 people in the population were 7 times higher among blacks (99) than among whites (15), and three times higher among Hispanics (50) than among whites.
- AIDS incidence rates were much lower among women (10) than among men (48)
- AIDS incidence remained relatively constant among men who have sex with men (decline of 2%) and IDUs (increase of 2%), but continued to increase substantially among people infected heterosexually (17% increase).

Trends in Mortality:

In 1995, the CDC AIDS surveillance system documented approximately 50,000 AIDS deaths. 1995 marked the smallest increase to date in AIDS deaths. During the first 2 quarters of 1996, the estimated number of AIDS deaths (22,000) was 12% less than the estimated number of AIDS deaths during the first two quarters of 1995 (24,900), marking the first decline in AIDS deaths since the beginning of the epidemic. Not surprisingly, trends in AIDS deaths closely parallel trends documented recently in AIDS incidence. AIDS deaths have not declined among women or among heterosexuals.

- AIDS deaths declined in all four regions of the country:
  (Northeast 15%, South 8%, Midwest 11%, West 16%)
- Deaths declined among men by 15% but increased among women by 3%.
- Deaths among MSM by 18% and 6% among IDUs, but increased 3% among heterosexuals.
- Deaths declined among all racial/ethnic groups, but declines were greater among whites (21%) than among blacks (2%) and Hispanics (10%).
- HIV infection remains the leading cause of death among 25-44 year olds, accounting for 19% of deaths in this age group.

Trends in AIDS Prevalence:

The number of people living with AIDS continues to increase. As of mid-1996, and estimated 223,000 people were living with AIDS.

- AIDS prevalence has increased 10% since mid-1995.
- The largest number of people living with AIDS by risk category are MSM (44%), followed by IDU (26%), and heterosexuals (12%).
- The greatest proportionate increase in AIDS prevalence from mid-1995 to mid-1996 occurred among those infected heterosexually (19%), while the greatest increase in the number of people living with AIDS occurred among MSM (5000).

DRAFT press release

EMBARGOED: 4 P.M. EST
Thursday, February 27, 1997

Contact: CDC, National Center
for HIV, STD and TB Prevention
Office of Health Communication
(404) 639-8895

CDC Report Documents First Ever Decline in AIDS Deaths in the U.S.

For the first time in the AIDS epidemic, there has been a marked decline in the number of deaths among people with AIDS, according to a report released today by the Centers for Disease Control and Prevention (CDC).

Today's CDC *Morbidity and Mortality Weekly Report* documents that deaths among people with AIDS declined 12% during the first six months of 1996, compared to the first six months of 1995.

"This is great news for all Americans living with AIDS and those who love them,"said Health and Human Services Secretary Donna E. Shalala. "Our sustained national investment in AIDS research, prevention, and treatment is paying a huge dividend for the American people."

The decline in AIDS deaths is likely due to improvements in recent years in treatments that delay the progression of HIV disease and prevent opportunistic infections, coupled with the success of prevention efforts in slowing the growth of the epidemic overall, CDC said. While it is too soon to determine the impact that the use of protease inhibitors as part of combination therapies will have on these trends, these therapies promise to further lengthen the lifespan of individuals living with HIV.

CDC reports that the estimated number of people diagnosed with AIDS in 1995 (AIDS incidence), increased just 2%, reflecting in part the ongoing success of HIV and AIDS prevention efforts. As AIDS incidence has stabilized, and deaths have begun to decrease, the number of

people living with AIDS (prevalence) has grown, rising 10% since mid-1995. AIDS prevalence will continue to increase, the CDC said, underscoring an increasing need for medical and other services for people living with AIDS and the critical need for prevention efforts to reduce the number of new HIV infections.

"As we continue to work to develop better treatment options, we must not lose sight of the fact that the best way to truly reduce the number of people who will die of AIDS is to prevent HIV infection in the first place," said CDC Director David Satcher, M.D, "Prevention remains our best and most cost-effective approach for bringing the HIV/AIDS epidemic under control and saving lives."

Trends in AIDS incidence and deaths varied by risk group, gender, and race, and both AIDS incidence and AIDS deaths continued to increase among women and among people infected through heterosexual contact . While AIDS deaths declined among all racial/ethnic groups, declines were much greater among whites (21%) than among blacks (2%) or Hispanics (10%). AIDS deaths rose among women (3%) and people infected through heterosexual contact (3%).

"We have made a great deal of progress in both prevention and treatment of AIDS, but declines have not yet been seen in all people. As we move forward into the next era in HIV and AIDS prevention, we must ensure we reach women and minority communities with effective prevention programs and provide access to quality care," Satcher stressed.

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Note: HHS press releases are available on the World Wide Web at: http://www.dhhs.gov.

The American Academy of Pediatrics

The American College of Obstetricians and Gynecologists

JOINT-STATEMENT OF THE AMERICAN ACADEMY OF PEDIATRICS THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

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

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

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

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

Approved: August 1995

The American Academy of Pediatrics 202/347-8600
The American College of Obstetricians and Gynecologists 202/863-2509

THIS LETTER WAS SENT TO SENATORS KASSEBAUM (R-KS), JEFFORDS (R-VT), FRIST (R-TN), KENNEDY (D-MA), AND DODD (D-CT), AND TO REPRESENTATIVES BLILEY (R-VA), BILIRAKIS (R-FL), COBURN (R-OK), WAXMAN (D-CA), AND STUDDS (D-MA).

The American Academy of Pediatrics

The American College of Obstetricians and Gynecologists

January 19, 1996

The Honorable Nancy Landon Kassebaum
United States Senate
302 Russell Senate Office Building
Washington, DC 20510

Dear Senator Kassebaum:

The House and Senate versions of the Ryan White CARE Reauthorization Act of 1995 contain two significantly different approaches to identifying the HIV status of pregnant women and newborns. As conferees work to resolve this issue, the American Academy of Pediatrics (AAP) and the American College of Obstetricians and Gynecologists (ACOG) write to share the expertise and experience of our national medical organizations.

We commend Congress for its commitment to address the complex issue of HIV counseling and testing for pregnant women and their newborns. As providers of health care for women and children, we are aware of the challenges in implementing these important prevention efforts. Thus, we urge you to recognize the complexities of these efforts when the conference committee revisits this issue by avoiding the adoption of policies that could hamper ongoing efforts of health care providers. In August of 1995, AAP and ACOG issued a joint statement (attached) which recommends that all pregnant women receive HIV education as part of their regular prenatal care. We further recommend that all pregnant women be tested for HIV with their consent.

Aggressive education and counseling, as part of a trusting and confidential doctor/patient relationship, are essential to stopping the spread of HIV. The AAP/ACOG joint statement closely reflects the Centers for Disease Control and Prevention (CDC) guidelines for HIV counseling and voluntary testing of pregnant women, which is the basis for the Senate provision in the Ryan White CARE Act. We believe that the CDC guidelines are the most effective and efficient approach to achieving a reduction in the transmission of HIV from mother to infant and strongly urge the conferees to adopt the Senate provision.

AAP and ACOG have two significant concerns about the HIV testing provision contained in the House legislation version. The bill recognizes the critical leadership role of national medical organizations in establishing mandatory HIV counseling and voluntary testing of pregnant women as a standard of care. However, by directing the standards medical organizations should set, the bill represents unnecessary and troubling government intrusion into private medical practice. We strongly urge conferees to exclude this provision in the final conference agreement.

In addition, the bill includes an important provision to protect individuals infected with HIV from health insurance discrimination but it does not go far enough. The language overlooks the need to protect women who may refuse HIV testing from the possibility of losing or being denied access to health insurance. Such discrimination also occurs when women with HIV seek other types of insurance and it is important that there be protections in the law for women, regardless of the reason for refusal of testing. If this provision is included in the final conference agreement, we strongly urge inclusion of language that also protects women who refuse HIV testing.

As the conference moves forward, we strongly urge that you adopt the Senate provision on HIV testing of pregnant women and newborns in the Ryan White CARE Reauthorization Act of 1995.

Sincerely,

Joe M. Sanders, MD

Joe M. Sanders, Jr., MD
Executive Director
American Academy of Pediatrics

Ralph W. Hale MD

Ralph W. Hale, MD
Executive Director
American College of Obstetricians and Gynecologists

July 1995

CDC CENTERS FOR DISEASE CONTROL AND PREVENTION

HIV/AIDS PREVENTION

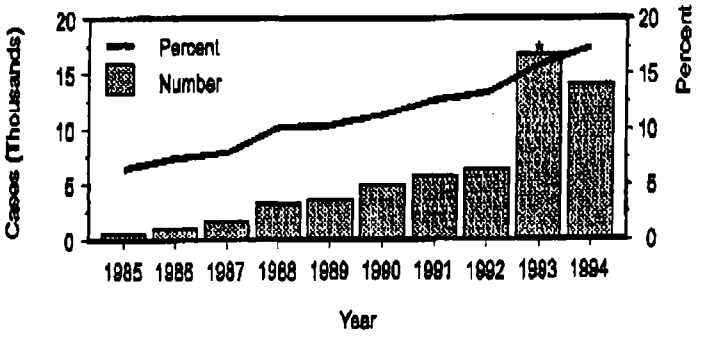
Women, Children, and HIV/AIDS

CDC tracks HIV infection and AIDS in two groups increasingly affected by the epidemic-- women and children--through a number of surveillance programs. Information on the status of HIV/AIDs in these groups is critical to plan and evaluate prevention programs, to determine health care resource needs, and to better target services and care to those who need them.

Women and Children Increasingly Affected by AIDS

Through December 1994, CDC received reports of 58,428 cumulative cases of AIDS among adult and adolescent women (13 years of age and older) in the U.S. Women account for more and more AIDS cases--they were only 7% of all AIDS cases in 1985, but jumped to 18% in 1994. AIDS is now the fourth leading cause of death among women 25-44. And AIDS is actually increasing faster in women than it is in men. In 1994 alone, 14,081 women were reported with AIDS. Women of childbearing age account for the vast majority of those cases: 84% were reported in women 15-44 years old.

FIGURE 1. Number and percentage of AIDS cases among women aged ≥13 years — United States, 1985–1994



* The AIDS surveillance case definition was expanded in 1993.

In 1994, most women with AIDS were infected through injecting drug use--41%. But nearly as many--38%--were infected through heterosexual contact with an infected partner. An additional 19% were initially reported with no specific HIV exposure. Historically, when these cases are investigated, it is found that most of these women--66%--have been exposed through heterosexual sex. Heterosexual contact is the most rapidly increasing transmission category for women. Comprehensive HIV prevention programs for women must address their multifaceted prevention needs.

The epidemic in children is closely associated with the epidemic in women. CDC has received reports of more than 5,500 cases among children who were infected with HIV through perinatal transmission (from mother to child during pregnancy, labor, or delivery) or by breastfeeding. In 1994, 1,017 pediatric AIDS cases were reported, an 8% increase from the number reported in 1993. Of these, 92% were mother-to-child transmission. For HIV-infected women of childbearing age, the possibility of perinatal transmission adds an additional important dimension to HIV prevention.

Racial/Ethnic and Regional Variations

- In 1994, women of color accounted for more than three-fourths of all AIDS cases among women: African-American women represented 57% and Hispanic women 20%.
- The Northeast accounted for the largest percentage of AIDS cases among women: 44%. The South followed with 36%; the West, 9%; Midwest, 7%; and Puerto Rico and U.S. territories, 4%.
- Most women with AIDS were from urban areas, but the South reported more than 10% of cases from smaller towns and rural areas.
- Of all AIDS cases among women, 61% were reported from just 5 states: New York (26%), Florida (13%), New Jersey (10%), California (7%), and Texas (5%).
- HIV infection in childbearing women varies by region. From 1989 to 1993, prevalence decreased in the Northeast from 4.1 to 3.4 per 1,000. In the South, it increased from 1.6 in 1989 to 2.0 in 1991, and has been stable since.

In 1993, an estimated 7,000 HIV-positive women gave birth in the U.S. That's 1 out of every 625 live births. Not every baby born to an infected mother is also infected. Without preventive treatment, the mother-to-child transmission rate is 15-30%, or about 1,000-2,000 infants in 1993.

AZT Can Reduce Perinatal Transmission

A breakthrough study last year showed that some pregnant women who are infected with HIV but don't yet have any signs of AIDS can reduce the chances of transmitting HIV to their babies by as much as two-thirds if AZT therapy is begun early in pregnancy, continued through labor and delivery, and provided to the child for the first 6 weeks of life.

Based on these findings, the Public Health Service (PHS) issued recommendations in August 1994 on using AZT to reduce the risk of perinatal transmission. And in July 1995, to provide pregnant women the opportunity to learn their HIV status as early in pregnancy as possible, PHS issued guidelines calling for routine counseling and voluntary HIV testing for all pregnant women. If women do not receive prenatal care, or if for any reason their HIV status is unknown at the time of delivery, the guidelines recommend that HIV testing be offered to them or their babies at or shortly after delivery. Implementing these guidelines will reduce the number of children who get AIDS. Just as important, targeted prevention programs for women are critical for the health of both women and children. The best way to prevent infection in babies is to prevent infection in women.

Evaluating Prevention Efforts

It is critical that resources are directed where they do the most good. To do that, the impact of prevention programs must be continuously monitored and changes made to most effectively target messages and activities. And surveillance is essential to know where HIV infection is decreasing, stabilizing, and increasing so that programs can be directed where they are most needed. In collaboration with community-based organizations, state and local health departments, and other federal and private-sector organizations, CDC is committed to ensuring that both the implementation and evaluation of HIV prevention programs for women and children continue to be priorities in the fight against AIDS.

CDC HIV/AIDS PREVENTION

CENTERS FOR DISEASE CONTROL AND PREVENTION

CDC Guidelines for HIV Counseling and Voluntary Testing for Pregnant Women

The Centers for Disease Control and Prevention (CDC) has published 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 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. If women do not receive prenatal care, or if for any reason their HIV status is unknown, the guidelines recommend that HIV testing be offered to the mothers or their babies at or shortly after labor and delivery.

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.

For More Information

The guidelines, were published on July 7, 1995, in the *Morbidity and Mortality Weekly Reports (MMWR)*. CDC developed the guidelines in conjunction with federal, state, and local health agencies, health and medical organizations, and members of the affected community. They were released in draft form in February and refined in response to input received during a 45-day public comment period.

Printed copies of the "U.S. Public Health Service Recommendations for HIV Counseling and Voluntary Testing for Pregnant Women" and "Recommendations of the U.S. Public Health Service Task Force on the Use of Zidovudine to Reduce Perinatal Transmission of Human Immunodeficiency Virus" (MMWR 1994;43[RR-11]) 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.

June 1995

Information for HIV Prevention Community Planning Groups (# 1)

CDC CENTERS FOR DISEASE CONTROL AND PREVENTION HIV/AIDS PREVENTION

Preventing Mother-to-Child HIV Transmission

Through December 1994, CDC received reports of 58,428 cumulative cases of AIDS among adult and adolescent women (13 years of age and older) in the U.S. Women account for more and more AIDS cases--they were only 7% of all AIDS cases in 1985, but jumped to 18% in 1994. AIDS is now the fourth leading cause of death among women 25-44. And AIDS is actually increasing faster in women than it is in men. In 1994 alone, 14,081 women were reported with AIDS. Women of childbearing age account for the vast majority of those cases: 84% were reported in women 15-44 years old.

Racial/Ethnic and Regional Variations

- In 1994, women of color accounted for more than three-fourths of all AIDS cases among women: African-American women represented 57% and Hispanic women 20%.
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- Most women with AIDS were from urban areas, but the South reported more than 10% of cases from smaller towns and rural areas.
- Of all AIDS cases among women, 61% were reported from just 5 states: New York (26%), Florida (13%), New Jersey (10%), California (7%), and Texas (5%).
- HIV infection in childbearing women varies by region. From 1989 to 1993, prevalence decreased in the Northeast from 4.1 to 3.4 per 1,000. In the South, it increased from 1.6 in 1989 to 2.0 in 1991, and has been stable since.

In 1994, most women with AIDS were infected through injecting drug use (41%); but nearly as many--38%--were infected through heterosexual contact with an infected partner. Heterosexual contact is the most rapidly increasing transmission category for women. Comprehensive HIV prevention programs for women must address their multifaceted prevention needs. For HIV-infected women of childbearing age, the possibility of perinatal transmission adds an additional important dimension to HIV prevention programs.

In 1993, an estimated 7,000 HIV-positive women gave birth in the U.S. That's 1 out of every 625 live births. Not every baby born to an infected mother is also infected. In fact, without preventive treatment, the mother-to-child (also known as perinatal or vertical) transmission rate is 15-30%, or about 1,000-2,000 infants in 1993.

AZT Reduces Perinatal Transmission of HIV

Last year, clinical trials in the U.S., Canada, and France conducted by America's National Institutes of Health and France's National Institute of Health and Medical Research (INSERM) showed that some HIV-infected women could reduce the risk of transmitting the virus to their babies by as much as *two-thirds* by taking AZT during pregnancy, labor and delivery, and by giving their babies AZT for the first 6 weeks after birth. For the first time--and the only time we know of so far--we can prevent HIV infection with a drug.

Some Unanswered Questions

The researchers established that AZT treatment was effective and caused no serious short-term side-effects for the mothers or infants. The NIH clinical trial included 477 women; during the study, 409 gave birth to 415 live infants. But several questions remain unanswered. The trial included women with HIV but no symptoms of AIDS, who had not previously taken AZT long-term, and who received prenatal care. AZT's effects may differ in women who don't match those characteristics. Researchers don't know if there would be changes in effectiveness with treatment variations, like using AZT only later in pregnancy or during labor and delivery, or using it for a shorter time in pregnancy. And they also don't know whether there are any long-term side-effects for mothers or children. NIH continues to monitor both mothers and children in the trial to answer these important questions.

But even with these unanswered questions, the finding that AZT treatment can reduce mother-to-child transmission by two-thirds is a true prevention breakthrough. Women should have the opportunity to choose whether to be tested and to choose whether to take AZT if they're HIV positive. Information is empowering.

Pregnant Women Should Be Counseled About HIV and Offered a Test

To take advantage of this prevention opportunity for their unborn children, women need to know they're HIV-infected well before giving birth. AZT therapy should begin about 14 weeks into the pregnancy. That's why new CDC guidelines recommend routine counseling and voluntary HIV testing for all pregnant women, as well as medical treatment before, during, and after birth. This approach has been endorsed by the major medical and public health professional organizations in the U.S., including the American Academy of Pediatrics, American College of Obstetricians and Gynecologists, American Nurses Association, Association of State and Territorial Health Officials, National Alliance of State and Territorial AIDS Directors, and American Public Health Association.

CDC Guidelines to Fight PCP in Children

When pregnant women know they're HIV positive, they can also take advantage of preventive treatment for *Pneumocystis carinii* pneumonia (PCP) for their babies. CDC guidelines issued in April 1995 recommend that all children perinatally exposed to HIV begin trimethoprim/sulfamethoxazole (TMP-SMX) treatment at 4-6 weeks and that HIV-infected infants should continue treatment until they're 12 months old. After 12 months, treatment decisions should be based on the child's CD4+ counts and whether s/he has had PCP.

What Does All This Mean for Community Planning Groups?

Community planning groups may wish to examine their epidemiologic profiles to assess the extent of perinatal transmission in their areas. Trends in transmission among women should be analyzed as specifically as possible to ascertain any geographic and racial/ethnic variations. A better understanding of the epidemic among women will help target specific prevention activities so they are most effective in reducing transmission.

Groups may also consider updating and expanding information about existing HIV prevention activities that target women, including pregnant women and women of childbearing age. Resource inventories should profile how existing providers of HIV counseling and testing services are incorporating information about the effectiveness of AZT in preventing perinatal transmission. Also, groups may wish to expand their resource inventories to profile all prenatal settings, considering whether prevention information is available and accessible and whether HIV counseling and testing are available on-site or through referral.

Where Do HIV+ Pregnant Women Get Care Now?

A recent ASTHO survey of states indicated that prenatal HIV counseling and testing and AZT therapy are happening most often as a collaborative effort between the state offices of HIV/AIDS and Family Planning or Maternal Child Health services. More than half the states responding reported they have policies or programs in place that address the health care needs of HIV-positive women. These programs are typically referrals to hospitals/consortia and Ryan White CARE Act programs.

A key component of comprehensive HIV prevention community plans is a description of how primary HIV prevention activities are linked to secondary HIV prevention activities (that is, activities to prevent or delay illness in people with HIV infection), including medical and social services. Community planning groups will want to understand fully the referral patterns for HIV-infected pregnant women, and to identify any potential gaps in service coordination and referral patterns. Groups should consider working closely with their jurisdiction's Ryan White group to understand the important linkages between prevention and care activities, especially for women at highest risk of HIV infection.

The new information on preventing perinatal transmission should also be considered by community planning groups as they evaluate the effectiveness of interventions to meet priority prevention needs. Groups may wish to consider whether to offer a targeted media campaign to make sure women get the information they need, whether counseling and testing services should be enhanced, whether referral mechanisms need to be strengthened or expanded, or whether other prevention interventions should be initiated or enhanced to ensure that pregnant women have every opportunity to know their HIV status, to understand the possible risks and benefits of AZT therapy, to take AZT if they choose so they can reduce the risk of HIV transmission to their babies, and to ensure their babies get the care they need after birth.

Want More Info?

The *Morbidity and Mortality Report* has carried the guidelines for AZT during pregnancy (MMWR 1994;43[RR-11]), routine counseling and voluntary testing (MMWR 1995;44[RR-7])), and PCP prevention (MMWR 1995;44[RR-4]). Call the National AIDS Clearinghouse: 1-800-458-5231.

CDC HIV/AIDS PREVENTION
CENTERS FOR DISEASE CONTROL AND PREVENTION

Prevention Communications
Division of HIV/AIDS Prevention

FACSIMILE TRANSMISSION

TO: Richard Sorian

Phone No.: 202/632-1204

Fax No.: 202/632-1096

FROM: Lydia Ogden
Prevention Communications

Phone No.: 404/639-0956*

Fax No.: 404/639-4333
***Toll-free, 24-hour message service:**
Phone 1-800-447-4784, then dial 329-1659

Date: 01/31/96

Number of Pages: 11
(Including this page)

Subject: Info on C&T guidelines

Comments: This is more than you asked for, but I thought it might be useful.... Hang in there. LO

FAX TRANSMISSION

U.S. Department of Health and Human Services
Office of the Secretary

DATE: 12/12

TO: Jon Klein

FAX:

PHONE:

FROM: Richard Sinai

Press Office, OASPA
Phone: (202) 690-6343
Fax: (202) 690-6247

TOTAL NUMBER OF PAGES TRANSMITTED:

COMMENTS:

They package those attacks in a bunch of focus-group-tested half truths designed to keep the public confused long enough to allow the legislation to pass.

And they have tucked away dozens of special interest provisions that give the illusion of softening the blow of these policies on our nation's health care system.

But the President and I have been working hard to make sure that members of Congress and the people of this country recognize the truth about these proposals.

Let me start with Medicare. The truth is, the Republican proposals would severely undermine the stability of the Medicare program and endanger the care that senior citizens and people with disabilities now receive.

I was amused to see Haley Barbour, the chairman of the Republican National Committee, offering a million dollar reward to anyone who can prove the Republicans are cutting Medicare.

I called June O'Neill, the director of the Congressional Budget Office, and told her she should call the RNC right away to collect.

But the people who are really going to need Mr. Barbour's generosity are the millions of senior citizens who are going to pay more and get less under the Republican Medicare scheme.

Because that is exactly what the GOP plan offers.

It would require senior citizens to pay an average of $140 dollars more in premiums every year and provides them with benefits that are worth $700 dollars less.

The Republican plan socks senior citizens with a one-two punch that will leave many of them reeling.

They increase out-of-pocket costs for beneficiaries by $50 billion dollars over seven years and they reduce spending by $220 billion dollars during that same time.

But beyond the numbers, the Republican Medicare plan contains a series of policy decisions that would cause permanent damage to this vital program.

The Republican sponsors say they are preserving the traditional Medicare program for any beneficiary who wants it. But at the same time they say that very program will "wither on the vine." Which is the truth?

important message of all, to continue to listen to people with HIV, to affected communities, to their care providers and their loved ones, and to work with all of us to be here for the cure.

Thank you again. (Applause.)

THE PRESIDENT: Thank you.

I want to ask one brief question, if I might. One of the difficulties that we have in dealing responsibly with this issue involves the dilemma that you just laid out when you said we ought to have voluntary testing, not mandatory testing. And the issue is most clearly represented with the whole question of pregnant women now given the advances that have been shown. I've studied the CDC guidelines; I think they're -- they make sense to me. I think the rest of us who don't know the facts ought to follow people that we hire to make these judgments. You know, if there's -- it makes a lot of sense to me. (Applause.)

But you just said that there were 34,000 people that needed your services, and only 10,000 were getting them and we had to find a way to get more people to get voluntarily tested. So how do we close the gap between 10,000 and 34,000? What can we do? What can you do? What can the rest of us do? That's what's driving this whole mandatory testing thing. It's not the notion that people are out there hiding, trying to avoid getting testing; it's that there's this huge gap and that society is being burdened by it, and so are these people. So how do we close that gap?

Q I know other speakers today will address, this but let me start. Mandatory testing not only will not address this problem, it will further drive people away and be a disincentive to their coming into care. (Applause.)

THE PRESIDENT: So how do you do it?

Q Mr. President, let me pick the single example of pregnant women. At Cook County Hospital, we have a program with our Ob-Gyn physicians in community health centers to engage pregnant women and women at risk of HIV in voluntary HIV counseling and testing. We have an exceptional compliance, well over 90 percent, with those efforts. You could not improve, and should not improve -- you can't force or use coercion in this kind of a public health problem. The first principle of public health is to engage the support and cooperation of the people.

There are many other creative strategies to reach people at risk. I think that Eileen and Sean have spoken to them, and I know you'll hear about more today.

MS. FLEMING: Mr. President, Phill Wilson was in the services workshop. He is the public policy director at AIDS Project Los Angeles, and an eloquent spokesperson on behalf of people living with HIV.

American Academy of Pediatrics

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Reply To:
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July 7, 1995

To: Karen Guss
The White House
Domestic Policy Council
FAX to 202-456-7431

From: Louis Z. Cooper, MD

Re: Impact of Mandatory HIV Testing on Infant Mortality

To follow is the excellent analysis of the potential impact of mandatory perinatal HIV testing on outcome of pregnancy in NY State. This material has not been released broadly, but was presented by then State Health Commissioner Chassin to Governor Cuomo's Task Force on Life and the Law. I had the opportunity to discuss this issue with that Task Force. I am unaware of what has happened to this group since the change in administration.

I believe this material strongly supports wisdom expressed by the new CDC recommendations and the Policy Statement on Perinatal HIV Testing of the American Academy of Pediatrics. I look forward to hearing from you as we all try to achieve public understanding and full implementation of the recommendations.

STATE OF NEW YORK - DEPARTMENT OF HEALTH

INTEROFFICE MEMORANDUM

TO: Mark R. Chassin, MD, Commissioner

FROM: Mary S. Applegate, M.D., M.P.H.
Division of Family Health

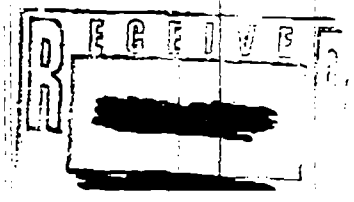
SUBJECT: Projected impact of mandatory HIV testing

DATE: September 27, 1994

Following our conversation last week, I have made several additions to the list of assumptions underlying the HIV/LBW model. I have described in greater detail the source of the data used to develop the model, and I have provided background information about the reasons for believing that PNC affects birth outcomes and that some high-risk women might be deterred from obtaining PNC by fear of learning their HIV status through mandatory testing.

I have also created 3 new models, changing the assumptions about the effectiveness of outreach and about the percentage of HIV+ women who would breastfeed. As you can see, the conclusions are completely unaffected by doubling the assumed impact of outreach. This new assumption does not change the point at which the reduction in cases of HIV among newborns is balanced by excess neonatal deaths due to LBW. For both assumptions about the impact of outreach the net benefit of mandatory testing is zero if 1% of high-risk women are deterred from obtaining PNC. The break even point for mandatory prenatal testing is at 6%-deterred using the more conservative assumption about outreach and at 7% using the more optimistic assumption. In contrast the model is more sensitive to changes in assumptions about breastfeeding rates. The break-even point for mandatory newborn testing shifts from 1% to over 2 1/2%, and for mandatory prenatal testing from 6% to 8% when the model assumes that 20% instead of 10% of the HIV+ mothers will breastfeed unless identified and warned. Including both of those new assumptions in the model (Table 6) does not change the break-even point compared with the model that includes only the increased breastfeeding rate. The attached tables and graphs showing the net results of the last four models (Figures 1 and 2) demonstrate these relationships more clearly.

In summary, this model suggests that a very small deterrent effect of mandatory testing on prenatal care use would erase the benefits of mandatory HIV testing. Regardless of the assumptions used, fewer than 3% of high risk women would have to be deterred from care for the net impact of mandatory newborn testing to be negative. For mandatory prenatal testing, the analogous point is between 6 and 8% deterred.



IMPACT OF MANDATORY HIV TESTING ON HIV TRANSMISSION AND ON NEONATAL MORTALITY

Assumptions Related to HIV Transmission

1. Roughly 1600 HIV+ women give birth annually in New York State, and currently half of them receive no prenatal care (PNC).

2. Aggressive outreach will reduce the number of women who receive no prenatal care by 10% (Tables 1, 3, and 5) or 20% (Tables 4 and 6).

3. With improvements in HIV counseling and testing protocols, the percentage of women tested will double:

   - from 35% to 70% in PNC;
   - from 20% to 40% in the OB Initiative.

   NOTE: Currently 73% of women in PNC receive HIV counselling, and 48% of counselled women consent to testing. Thus the proportion of all women in PNC who receive HIV testing is 35%.

4. **TABLE 1:** All women who know that they are HIV+ and who are in prenatal care will take zidovudine (AZT), and none of them will breastfeed. Their mother-to-child HIV transmission rate will be 8%.

   TABLES 2-6: Only 85% of known HIV+ women will take AZT.

5. The transmission rate during pregnancy and birth for those who do not take AZT is 25%.

6. The rate of postnatal transmission is 15% among those who breastfeed.
   Tables 1-4: 10% of HIV+ women will breastfeed unless identified as HIV+ and warned not to breastfeed. None will breast feed if advised not to.
   Tables 5-6: 20% of HIV+ women will breastfeed unless identified.

   NOTE: Data from a Ross Laboratories survey of breastfeeding indicate that even with active promotion of breastfeeding, only 37% of WIC-enrolled, low-income women breastfeed. Furthermore, NYS AIDS Registry data indicate that two-thirds of mothers who transmit HIV infection to their infants are intravenous drug users, and all drug

users are routinely discouraged from breastfeeding due to concern about drug exposure for the infant. An informal survey of NYC providers who care for high-risk women suggests that the actual breastfeeding rate in this high-risk group is less than 10%.

7. The results of HIV testing done at birth (through the OB Initiative or mandatory newborn testing) will be available in time to prevent transmission related to breastfeeding. In fact, since results would not be available until several weeks postpartum, HIV testing at the time of birth would probably reduce but not eliminate transmission via breastfeeding. Therefore, the projections that follow overestimate the benefit of mandatory HIV testing at the time of birth.

Assumptions Related to Neonatal Mortality

1. Calculations are based on 290,000 births/year: 7,000 with no PNC, 77,000 with late (2nd or 3rd trimester) entry into PNC, and the rest with early PNC (based roughly on 1992 birth certificate data).

2. Aggressive outreach will reduce the number of women who receive little of no prenatal care (PNC). The impact of outreach on receipt of PNC will be incremental: outreach to women who currently get no PNC will bring them into care late in pregnancy, while outreach to those who currently receive late care will bring them into care early.
Tables 1, 2, 3 and 5 assume that outreach will affect 10% of women in each category.
Tables 4 and 6 assume a 20% affect.

3. Rates of moderately low and very low birthweight vary with amount of PNC as follows:

	MLBW	VLBW
no PNC	15%	7%
Late PNC	6%	2%
Early PNC	2%	1%

(based on 1992 birth certificate data).

4. **TABLES 1 and 2:** Providing prenatal care to women who now get none will make their risk of low birth weight and very low birth weight equivalent to the rates for women who now receive prenatal care, i.e. it will eliminate <u>all</u> of their excess risk.

   TABLES 3 and 6: Providing PNC to women who now get none will eliminate <u>half</u> of their excess risk of LBW and VLBW.

   NOTE: It is not possible to measure the impact of prenatal care precisely. Some of the differences in outcomes between women who receive care early and those who receive none are not due to the PNC visits themselves, but to underlying differences in the groups of women. Some of these differences -- e.g. age, race, SES, smoking, and pre-pregnancy weight -- can be accounted for in studies of prenatal care. Other important factors are much more intangible or hard to measure: wantedness of the pregnancy, motivation to practice healthy habits, social support, drug use. Despite these difficulties there is strong evidence that prenatal care has a beneficial impact on pregnancy outcomes. Several studies have shown, moreover, that the impact of comprehensive PNC is greatest among the most disadvantaged women. Middle class women who are already healthy and well-nourished may gain little additional benefit from PNC. Poor women whose baseline health status is more marginal have been shown to benefit significantly from the medical care, nutritional support, psychosocial counselling, and health education that are part of comprehensive prenatal care. Because the exact magnitude of the impact of PNC cannot be measured, most of the models that follow assume a moderate impact, as described above.

5. Birthweight specific neonatal mortality rates (per 1000 live births) are: 252 at birthweights under 1500 grams; 11.6 at birthweights 1500-2499 grams; and 1.2 at birthweights of 2500 grams and above (based on 1993 SPARCS data).

<u>Assumptions about Avoidance of Prenatal Care</u>

1. Voluntary HIV testing programs will have no impact on prenatal care attendance rates.

2. Women who do not perceive themselves to be at risk for HIV infection will not be affected by mandatory testing.

3. Out of 290,000 births/year in NYS, approximately 44,800 women will perceive themselves to be at risk for HIV, either because of drug use (11,200--reported on 1992 birth certificates) or because of sexual behavior (three times the number of drug users--see note).

   Ten percent (4,480) of these women currently receive no PNC, and an additional 30% (13,440) receive late care (based on birth certificate data about PNC rates among drug-users).

NOTE: According to data from the NYS AIDS Registry, half as many childbearing women are infected through heterosexual exposure as through IV drug use. This model assumes that many more women will perceive that they are at sexual risk of HIV infection, but there are no concrete data on this specific issue.

4. If mandatory HIV testing is implemented, a small fraction of the 40,320 high risk women who currently do get PNC may avoid care because of fear of learning their HIV status.

   Separate estimates were calculated assuming that 0%, 1%, 5%, and 10% of these high-risk women would be deterred from receiving prenatal care by fear of mandatory testing.

   NOTE: A 1992 Columbia University study of HIV counselling in NYS's family planning and prenatal care programs found that 50% of women turned down offers of HIV testing. The chief reason given (by 40% of those who refused testing) was that they did not want to know their HIV status. The percentage of women who refused testing was highest (70%) among those who perceived themselves to be at high-risk for HIV infection.

5. For this analysis, women at high risk of HIV infection are assumed to have the same risk of LBW as other women receiving equivalent PNC.

6. The deterrent effect of mandatory testing is all-or-nothing: women may avoid PNC entirely, but they will not simply delay entry into care.

NOTE: Mandatory newborn testing may also lead to an increase in unattended home births, but we have no data on which to base projections of either the magnitude or impact of this.

Sources of Data

1. Vital Records – The New York State Department of Health collects data on births and deaths in New York through birth and death certificates. Birth certificates collect a wide range of data on such issues as date of entry into prenatal care, number of prenatal visits, health risk factors for mother and infant, and demographic variables.

2. SPARCS (Statewide Planning and Resource Cooperative System) is a rich database with information about all hospital discharges in New York State. Because hospital reimbursement is linked to SPARCS, this database provides a very complete record of hospitalizations, including data about diagnoses, discharge status (alive or dead), and limited demographic information. Since over 95% of all births occur in hospitals, it provides a useful complement to vital records data related to births.

3. New York State AIDS Registry – Several dozen communicable diseases are designated as "reportable" in New York State, meaning that health care providers, clinical laboratories, and local health departments are required to inform the NYSDOH of all individualls with those diseases. AIDS (but not simply HIV infection) is a reportable disease. The AIDS Registry contains information on all individuals with AIDS reported to the Department, including age and source of infection (e.g. intravenous drug use, heterosexual contact). Since mother-to-child transmission is responsible for the vast majority of cases of AIDS in children, the Registry also includes data on the *mother's* source of infection in cases of pediatric AIDS.

Projected Impact of Mandatory HIV Testing on Neonatal Mortality and HIV Cases

Summary of Differences Among Six Models

	Zidovudine acceptance rate among HIV+ pregnant women	Effectiveness of prenatal care[1]	Effectiveness of outreach[2]	Breastfeeding rate among HIV+ women unaware of their HIV status[3]
Model 1	100%	All	10%	10%
Model 2	85%	All	10%	10%
Model 3	85%	Half	10%	10%
Model 4	85%	Half	20%	10%
Model 5	85%	Half	10%	20%
Model 6	85%	Half	20%	20%

[1]Among groups who receive different amounts of prenatal care (none vs. late vs. adequate), the fraction of variation in low-birthweight rates that is attributable to differences in amount of prenatal care. For example, women with no prenatal care have a 7% risk of delivering a very low birthweight infant, while women with adequate care have a 1% risk. Models 1 and 2 assume that providing adequate prenatal care for women who currently receive none can eliminate *all* their excess risk, reducing their risk to 1%. The other models assume that providing these women with adequate care will only eliminate *half* of their excess risk (reducing their risk to 4%), with the remaining excess risk attributable to inherent differences in the women, e.g. poor nutritional status, disinterest in the pregnancy, drug use.

[2]Proportion of women with late or no prenatal care currently who will receive more adequate care in the future because of outreach efforts.

[3]All models assume that women who know that they are HIV+ will NOT breastfeed.

Projected Impact of Mandatory HIV Testing on Neonatal Mortality and HIV Cases

Summary of Results

If mandatory HIV testing deters women who are at high risk for HIV infection from obtaining prenatal care, the resulting increased number of neonatal deaths due to LBW may outweigh the number of cases of HIV transmission prevented. The following chart shows the "break-even point" at which the number of excess neonatal deaths due to LBW equals the number of cases of HIV transmission prevented. Percentages represent the fraction of *women at high risk for HIV infection* who are deterred from prenatal care.

	"Break-even" point for mandatory newborn testing (% of *high-risk* women deterred from receiving prenatal care)
Model 1	1.1%
Model 2	1.2%
Model 3	1.2%
Model 4	1.3%
Model 5	2.6%
Model 6	2.7%

Projected Impact of Mandatory HIV Testing on Neonatal Mortality and HIV Cases

Summary of Results

If mandatory HIV testing deters women who are at high risk for HIV infection from obtaining prenatal care, the resulting increased number of neonatal deaths due to LBW may outweigh the number of cases of HIV transmission prevented. The following chart shows the "break-even point" at which the number of excess neonatal deaths due to LBW equals the number of cases of HIV transmission prevented. Percentages represent the fraction of *women at high risk for HIV infection* who are deterred from prenatal care.

	"Break-even" point for mandatory testing (% of *high-risk* women deterred from receiving prenatal care)	
	Newborn testing	Prenatal testing
Model 1	1.1%	6.6%
Model 2	1.2%	6.4%
Model 3	1.2%	6.0%
Model 4	1.3%	7.0%
Model 5	2.6%	7.8%
Model 6	2.7%	8.2%

Figure 1. Net effect of mandatory newborn HIV testing: LBW deaths vs. HIV cases.

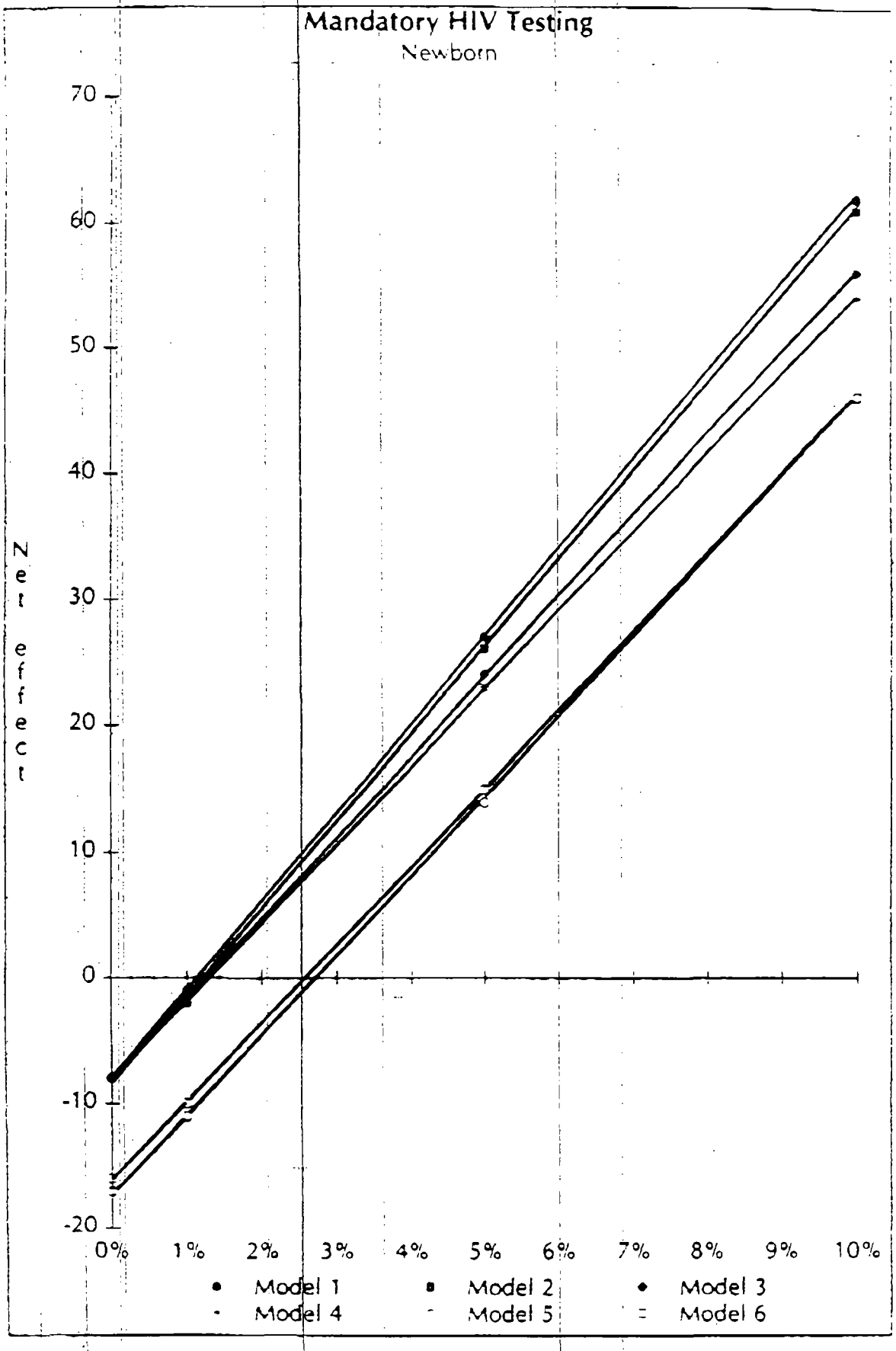
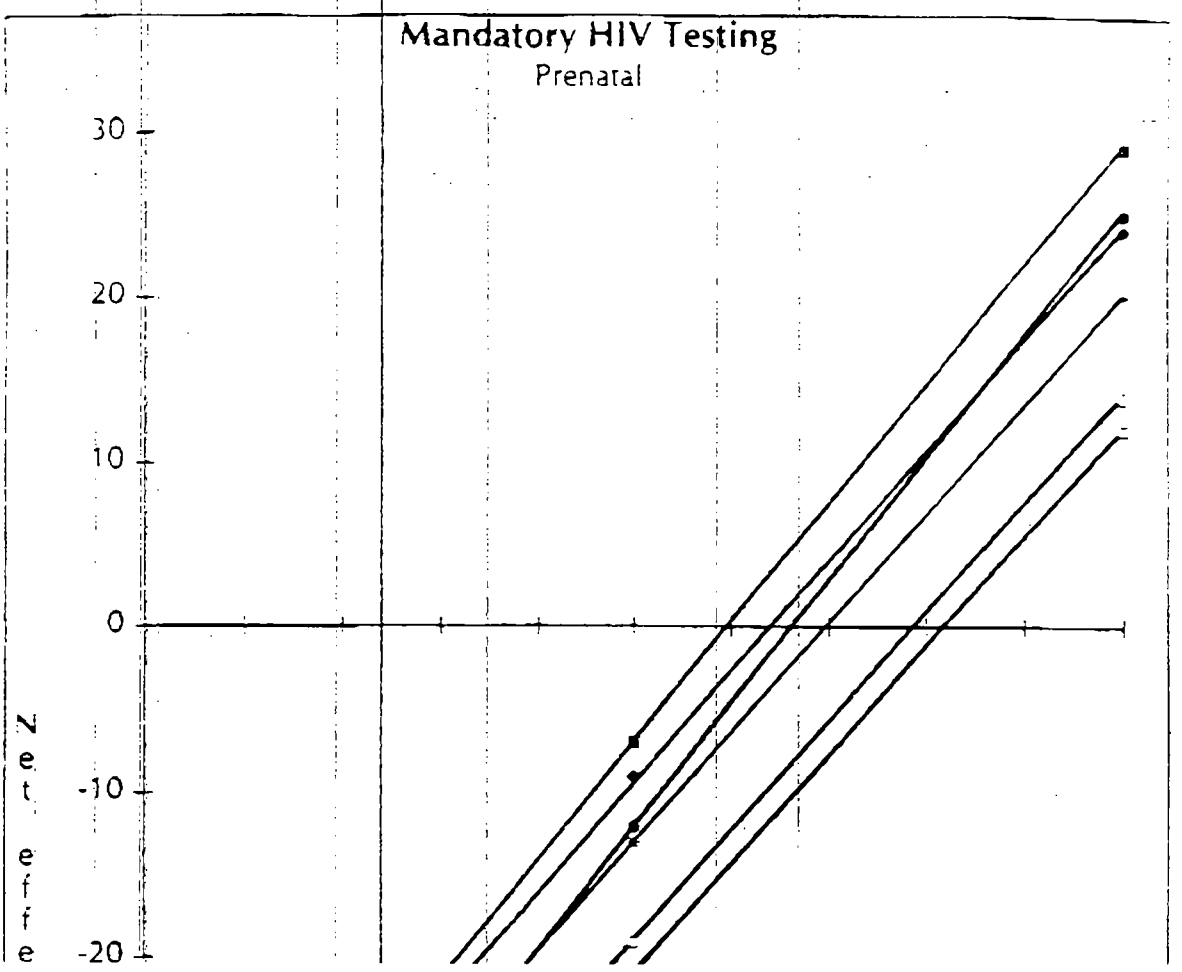


Figure 2. Net effect of mandatory prenatal HIV testing: LBW deaths vs. HIV cases.



Model 1.

PROJECTED IMPACT OF MANDATORY HIV TESTING ON MOTHER-TO-CHILD HIV TRANSMISSION AND ON NEONATAL MORTALITY

No change in PNC or testing rates.	356 / 1506
Outreach increases PNC; testing rates unchanged.	350 / 1475
Outreach + double HIV testing rates (voluntary) new baseline	296 / 1475
All of above + mandatory newborn testing	288 (-8) / 1475 (0) (-8)

KEY:

HIV-infected infants (*) / LBW-related neonatal deaths (**) (#)

(* = cases prevented compared w/ no mandatory testing)
(** = excess deaths related to avoidance of PNC)
(# = net effect: excess LBW deaths - HIV cases prevented)

September 21, 1994

ASSUMPTIONS:

100% acceptance of zidovudine
full impact of prenatal care
10% impact of outreach
10% breastfeeding rate

Model 1.

PROJECTED IMPACT OF MANDATORY HIV TESTING ON MOTHER-TO-CHILD HIV TRANSMISSION AND ON NEONATAL MORTALITY

KEY:

HIV-infected infants (*) / LBW related neonatal deaths (**) / # = net effect

(* = cases prevented compared w/ no mandatory testing)
(** = excess deaths related to avoidance of PNC)
(# = net effect: excess LBW deaths - HIV cases prevented)

	% of women at risk for HIV who are deterred from PNC		
	1%	5%	10%
No change in PNC or testing rates.	356 / 1506		
Outreach increases PNC; testing rates unchanged.	350 / 1475		
Outreach + double HIV testing rates (voluntary) new baseline	296 / 1475		
All of above + mandatory newborn testing	288 (-8) / 1475 (0) (-8)	289 (-7) / 1481 (+6) (-1)	292 (-4) / 1506 (+31) (+27)	296 (0) / 1537 (+62) (+42)

September 21, 1994

ASSUMPTIONS:
100% acceptance of zidovudine
full impact of prenatal care
10% impact of outreach
10% breastfeeding rate

Model 1.

PROJECTED IMPACT OF MANDATORY HIV TESTING ON MOTHER-TO-CHILD HIV TRANSMISSION AND ON NEONATAL MORTALITY

KEY:

HIV-infected infants (*)

LBW-related neonatal deaths (**)

(* = cases prevented compared w/ no mandatory testing)
(** = excess deaths related to avoidance of PNC)
(# = net effect: excess LBW deaths - HIV cases prevented)

		% of women at risk for HIV who are deterred from PNC		
		1%	5%	10%
No change in PNC or testing rates.	356 / 1506			
Outreach increases PNC; testing rates unchanged.	350 / 1475			
Outreach + double HIV testing rates (voluntary) new baseline	296 / 1475			
All of above + mandatory newborn testing	288 (-8) / 1475 (0)	289 (-7) / 1481 (+6)	292 (-4) / 1506 (+31)	296 (0) / 1537 (+62)
All of above + mandatory prenatal testing	247 (-49) / 1475 (0)	248 (-48) / 1481 (+6)	253 (-43) / 1506 (+31)	259 (-37) / 1537 (+62)

ASSUMPTIONS:
- 100% acceptance of zidovudine
- full impact of prenatal care
- 10% impact of outreach
- 10% breastfeeding rate

September 21, 1994

Model 2.

PROJECTED IMPACT OF MANDATORY HIV TESTING ON MOTHER-TO-CHILD HIV TRANSMISSION AND ON NEONATAL MORTALITY

	HIV-infected infants (*) / LBW-related neonatal deaths (**)
No change in PNC or testing rates.	365 / 1506
Outreach increases PNC; testing rates unchanged.	360 / 1475
Outreach + double HIV testing rates (voluntary) new baseline	313 / 1475
All of above + mandatory newborn testing	305 (-8) / 1475 (0) (-8)

KEY:

HIV-infected infants (*) / LBW-related neonatal deaths (**) (#)

(* = cases prevented compared w/ no mandatory testing)
(** = excess deaths related to avoidance of PNC)
(# = net effect: excess LBW deaths - HIV cases prevented)

September 21, 1994

ASSUMPTIONS:

85% acceptance of zidovudine
full impact of prenatal care
10% impact of outreach
10% breastfeeding rate

Model 2.

PROJECTED IMPACT OF MANDATORY HIV TESTING ON MOTHER-TO-CHILD HIV TRANSMISSION AND ON NEONATAL MORTALITY

KEY:

HIV-infected infants (*) / LBW-related neonatal deaths (**)

(# = net effect: excess LBW deaths - HIV cases prevented)

(* = cases prevented compared w/ no mandatory testing)

(** = excess deaths related to avoidance of PNC)

No change in PNC or testing rates.	365 / 1506
Outreach increases PNC; testing rates unchanged.	360 / 1475
Outreach + double HIV testing rates (voluntary) new baseline	313 / 1475

% of women at risk for HIV who are deterred from PNC

All of above + mandatory newborn testing	1%	5%	10%
	305 (-8) / 1475 (0) (-8)	305 (-6) / 1481 (+6) (-2)	308 (-5) / 1506 (+31) (+26)	312 (-1) / 1537 (+62) (+61)

ASSUMPTIONS:

85% acceptance of zidovudine
full impact of prenatal care
10% impact of outreach
10% breastfeeding rate

September 21, 1994

Model 2.

PROJECTED IMPACT OF MANDATORY HIV TESTING ON MOTHER-TO-CHILD HIV TRANSMISSION AND ON NEONATAL MORTALITY

KEY:

HIV-infected infants (*) / LBW-related neonatal deaths (**) / # = net effect

(* = cases prevented compared w/ no mandatory testing)
(** = excess deaths related to avoidance of PNC)
(# = net effect: excess LBW deaths - HIV cases prevented)

		% of women at risk for HIV who are deterred from PNC		
		1%	5%	10%
No change in PNC or testing rates.	365 / 1506			
Outreach increases PNC; testing rates unchanged.	360 / 1475			
Outreach + double HIV testing rates (voluntary) new baseline	313 / 1475			
All of above + mandatory newborn testing	305 (-8) / 1475 (0)	305 (-8) / 1481 (+6)	308 (-5) / 1506 (+31)	312 (-1) / 1537 (+62)
All of above + mandatory prenatal testing	270 (-43) / 1475 (0)	271 (-42) / 1481 (+6)	275 (-38) / 1506 (+31)	280 (-33) / 1537 (+62)

September 21, 1994

ASSUMPTIONS:
85% acceptance of zidovudine
full impact of prenatal care
10% impact of outreach
10% breastfeeding rate

Model 3.

PROJECTED IMPACT OF MANDATORY HIV TESTING ON MOTHER-TO-CHILD HIV TRANSMISSION AND ON NEONATAL MORTALITY

	HIV-infected infants (*) / LBW-related neonatal deaths (#)
No change in PNC or testing rates.	365 / 1596
Outreach increases PNC; testing rates unchanged.	360 / 1490
Outreach + double HIV testing rates (voluntary) new baseline	313 / 1490
All of above + mandatory newborn testing	305 (-8) / 1490 (0) (-8)

KEY:

HIV-infected infants (*) / LBW-related neonatal deaths (#)

(* = cases prevented compared w/ no mandatory testing)
(** = excess deaths related to avoidance of PNC)
(# = net effect: excess LBW deaths - HIV cases prevented)

September 21, 1994

ASSUMPTIONS:

85% acceptance of zidovudine
partial impact of prenatal care
10% impact of outreach
10% breastfeeding rate

Model 3.

PROJECTED IMPACT OF MANDATORY HIV TESTING ON MOTHER-TO-CHILD HIV TRANSMISSION AND ON NEONATAL MORTALITY

KEY:

HIV-infected infants (*) / LBW-related neonatal deaths (**) / (#)

(* = cases prevented compared w/ no mandatory testing)
(** = excess deaths related to avoidance of PNC)
(# = net effect: excess LBW deaths - HIV cases prevented)

		% of women at risk for HIV who are deterred from PNC		
		1%	5%	10%
No change in PNC or testing rates.	365 / 1506			
Outreach increases PNC; testing rates unchanged.	360 / 1490			
Outreach + double HIV testing rates (voluntary) new baseline	313 / 1490			
All of above + mandatory newborn testing	305 (-8) / 1490 (0); (#) -8	305 (-8) / 1496 (+6); (#) -2	308 (-5) / 1519 (+29); (#) +24	312 (-1) / 1547 (+57); (#) +52

ASSUMPTIONS:
85% acceptance of zidovudine
partial impact of prenatal care
10% impact of outreach
10% breastfeeding rate

September 21, 1994

Model 3.

PROJECTED IMPACT OF MANDATORY HIV TESTING ON MOTHER-TO-CHILD HIV TRANSMISSION AND ON NEONATAL MORTALITY

KEY:

HIV-infected infants (*) / LBW-related neonatal deaths (**) / (#)

(* = cases prevented compared w/ no mandatory testing)
(** = excess deaths related to avoidance of PNC)
(# = net effect: excess LBW deaths - HIV cases prevented)

% of women at risk for HIV who are deterred from PNC

		1%	5%	10%
No change in PNC or testing rates.	365 / 1506			
Outreach increases PNC; testing rates unchanged.	360 / 1490			
Outreach + double HIV testing rates (voluntary) new baseline	313 / 1490			
All of above + mandatory newborn testing	305 (-8) / 1490 (0) (-8)	305 (-8) / 1496 (+6) (-2)	308 (-5) / 1519 (+29) (+24)	312 (-1) / 1547 (+57) (+56)
All of above + mandatory prenatal testing	270 (-43) / 1490 (0) (-43)	271 (-42) / 1496 (+6) (-36)	275 (-38) / 1519 (+29) (-9)	280 (-33) / 1547 (+57) (+34)

ASSUMPTIONS:
85% acceptance of zidovudine
partial impact of prenatal care
10% impact of outreach
10% breastfeeding rate

September 21, 1994

Model 4.

PROJECTED IMPACT OF MANDATORY HIV TESTING ON MOTHER-TO-CHILD HIV TRANSMISSION AND ON NEONATAL MORTALITY

No change in PNC or testing rates.	365 / 1506
Outreach increases PNC; testing rates unchanged.	356 / 1475
Outreach + double HIV testing rates (voluntary) new baseline	307 / 1475
All of above + mandatory newborn testing	299 (-8) / 1475 (0) ; (-8)

KEY:

HIV-infected infants (*) / LBW-related neonatal deaths (**) ; (#)

(* = cases prevented compared w/ no mandatory testing)
(** = excess deaths related to avoidance of PNC)
(# = net effect: excess LBW deaths - HIV cases prevented)

September 21, 1994

ASSUMPTIONS:
85% acceptance of zidovudine
partial impact of prenatal care
20% impact of outreach
10% breastfeeding rate

Model 4.

PROJECTED IMPACT OF MANDATORY HIV TESTING ON MOTHER-TO-CHILD HIV TRANSMISSION AND ON NEONATAL MORTALITY

KEY:

HIV-infected infants (*) / LBW-related neonatal deaths (**)

(# = net effect: excess LBW deaths - HIV cases prevented)

(* = cases prevented compared w/ no mandatory testing)
(** = excess deaths related to avoidance of PNC)

		% of women at risk for HIV who are deterred from PNC		
		1%	5%	10%
No change in PNC or testing rates.	365 / 1506			
Outreach increases PNC; testing rates unchanged.	356 / 1475			
Outreach + double HIV testing rates (voluntary) now baseline	307 / 1475			
All of above + mandatory newborn testing	299 (-8) / 1475 (0); # -8	299 (-8) / 1481 (+6); # -2	302 (-5) / 1503 (+28); # +22	305 (-2) / 1531 (+56); # +54

ASSUMPTIONS:
- 85% acceptance of zidovudine
- partial impact of prenatal care
- 20% impact of outreach
- 10% breastfeeding rate

September 21, 1994

Model 4.

PROJECTED IMPACT OF MANDATORY HIV TESTING ON MOTHER-TO-CHILD HIV TRANSMISSION AND ON NEONATAL MORTALITY

KEY:

HIV-infected infants (*)

LBW-related neonatal deaths (**)

(# = net effect: excess LBW deaths - HIV cases prevented)

(* = cases prevented compared w/ no mandatory testing)

(** = excess deaths related to avoidance of PNC)

	% of women at risk for HIV who are deterred from PNC		
	1%	5%	10%
No change in PNC or testing rates.	365 / 1506		
Outreach increases PNC; testing rates unchanged.	356 / 1475		
Outreach + double HIV testing rates (voluntary) now baseline	307 / 1475		
All of above + mandatory newborn testing	299 (-8) / 1475 (0); (#) -8	299 (-8) / 1481 (+6); (#) -2	302 (-5) / 1503 (+28); (#) +23	305 (-2) / 1531 (+56); (#) +54
All of above + mandatory prenatal testing	261 (-46) / 1475 (0); (#) -46	262 (-45) / 1481 (+6); (#) -39	266 (-41) / 1503 (+28); (#) -13	271 (-36) / 1531 (+56); (#) +20

September 21, 1994

ASSUMPTIONS:

- 85% acceptance of zidovudine
- partial impact of prenatal care
- 20% impact of outreach
- 10% breastfeeding rate

Model 5.

PROJECTED IMPACT OF MANDATORY HIV TESTING ON MOTHER-TO-CHILD HIV TRANSMISSION AND ON NEONATAL MORTALITY

	HIV infected infants (*) / LBW-related neonatal deaths (**)
No change in PNC or testing rates.	380 / 1506
Outreach increases PNC; testing rates unchanged.	374 / 1475
Outreach + double HIV testing rates (voluntary) new baseline	322 / 1475
All of above + mandatory newborn testing	305 (-17) / 1475 (0) (-17)

KEY:

HIV infected infants (*) / LBW-related neonatal deaths (**) (#)

(* = cases prevented compared w/ no mandatory testing)
(** = excess deaths related to avoidance of PNC)
(# = net effect: excess LBW deaths - HIV cases prevented)

September 21, 1994

ASSUMPTIONS:

85% acceptance of zidovudine
partial impact of prenatal care
10% impact of outreach
20% breastfeeding rate

Model 5.

PROJECTED IMPACT OF MANDATORY HIV TESTING ON MOTHER-TO-CHILD HIV TRANSMISSION AND ON NEONATAL MORTALITY

KEY:

HIV-infected infants (*) / LBW-related neonatal deaths (**)

(# = net effect)

(* = cases prevented compared w/ no mandatory testing)
(** = excess deaths related to avoidance of PNC)
(# = net effect: excess LBW deaths - HIV cases prevented)

		% of women at risk for HIV who are deterred from PNC		
		1%	5%	10%
No change in PNC or testing rates.	380 / 1506			
Outreach increases PNC; testing rates unchanged.	374 / 1475			
Outreach + double HIV testing rates (voluntary) new baseline	322 / 1475			
All of above + mandatory newborn testing	305 (-17) / 1475 (0) (#-17)	305 (-17) / 1481 (+6) (#-11)	308 (-14) / 1503 (+28) (#+14)	312 (-10) / 1531 (+56) (#+42)

September 21, 1994

ASSUMPTIONS:
85% acceptance of zidovudine
partial impact of prenatal care
10% impact of outreach
20% breastfeeding rate

Model 5.

PROJECTED IMPACT OF MANDATORY HIV TESTING ON MOTHER-TO-CHILD HIV TRANSMISSION AND ON NEONATAL MORTALITY

KEY:

HIV-infected infants (*)

LBW-related neonatal deaths (**)

(# = net effect: excess LBW deaths - HIV cases prevented)

(* = cases prevented compared w/ no mandatory testing)
(** = excess deaths related to avoidance of PNC)

% of women at risk for HIV who are deterred from PNC

		1%	5%	10%
No change in PNC or testing rates.	380 / 1506			
Outreach increases PNC; testing rates unchanged.	374 / 1475			
Outreach + double HIV testing rates (voluntary) new baseline	322 / 1475			
All of above + mandatory newborn testing	305 (-17) / 1475 (0)	305 (-17) / 1481 (+6)	308 (-14) / 1503 (+28)	312 (-10) / 1531 (+56)
All of above + mandatory prenatal testing	270 (-52) / 1475 (0)	271 (-51) / 1481 (+6)	275 (-47) / 1503 (+28)	280 (-42) / 1531 (+56)

September 21, 1994

ASSUMPTIONS:

85% acceptance of zidovudine
partial impact of prenatal care
10% impact of outreach
20% breastfeeding rate

Model 6.

PROJECTED IMPACT OF MANDATORY HIV TESTING ON MOTHER-TO-CHILD HIV TRANSMISSION AND ON NEONATAL MORTALITY

No change in PNC or testing rates.	380 / 1506
Outreach increases PNC; testing rates unchanged.	371 / 1475
Outreach + double HIV testing rates (voluntary) new baseline	315 / 1475
All of above + mandatory newborn testing	299 (-16) / 1475 (0) (-16)

KEY:

HIV-infected infants (*) / LBW-related neonatal deaths (**) (#)

(* = cases prevented compared w/ no mandatory testing)
(** = excess deaths related to avoidance of PNC)
(# = net effect: excess LBW deaths - HIV cases prevented)

September 21, 1994

ASSUMPTIONS:

85% acceptance of zidovudine
partial impact of prenatal care
20% impact of outreach
20% breastfeeding rate

Model 6.

PROJECTED IMPACT OF MANDATORY HIV TESTING ON MOTHER-TO-CHILD HIV TRANSMISSION AND ON NEONATAL MORTALITY

KEY:

HIV-infected infants (*) / LBW-related neonatal deaths (**)

(# = net effect: excess LBW deaths - HIV cases prevented)

(* = cases prevented compared w/ no mandatory testing)
(** = excess deaths related to avoidance of PNC)

	% of women at risk for HIV who are deterred from PNC		
	1%	5%	10%
No change in PNC or testing rates.	380 / 1506		
Outreach increases PNC; testing rates unchanged.	371 / 1475		
Outreach + double HIV testing rates (voluntary) new baseline	315 / 1475		
All of above + mandatory newborn testing	299 (-16) / 1475 (0) (#: -16)	299 (-16) / 1481 (+6) (#: -10)	302 (-13) / 1503 (+28) (#: +15)	305 (-10) / 1531 (+56) (#: +46)

September 21, 1994

ASSUMPTIONS:

85% acceptance of zidovudine
partial impact of prenatal care
20% impact of outreach
20% breastfeeding rate

Model 6.

PROJECTED IMPACT OF MANDATORY HIV TESTING ON MOTHER-TO-CHILD HIV TRANSMISSION AND ON NEONATAL MORTALITY

KEY:

HIV-infected infants (*)

LBW-related neonatal deaths (**)

(# = net effect)

(* = cases prevented compared w/ no mandatory testing)
(** = excess deaths related to avoidance of PNC)
(# = net effect: excess LBW deaths - HIV cases prevented)

		% of women at risk for HIV who are deterred from PNC		
		1%	5%	10%
No change in PNC or testing rates.	380 / 1506			
Outreach increases PNC; testing rates unchanged.	371 / 1475			
Outreach + double HIV testing rates (voluntary) new baseline	315 / 1475			
All of above + mandatory newborn testing	299 (-16) / 1475 (0)	299 (-16) / 1481 (+6)	302 (-13) / 1503 (+28)	305 (-10) / 1531 (+36)
All of above + mandatory prenatal testing	261 (-54) / 1475 (0)	262 (-53) / 1481 (+6)	266 (-49) / 1503 (+28)	271 (-44) / 1531 (+56)

September 21, 1994

ASSUMPTIONS:
85% acceptance of zidovudine
partial impact of prenatal care
20% impact of outreach
20% breastfeeding rate

Projected Impact of Mandatory Newborn HIV Testing on Neonatal Mortality and Mother-Child HIV Transmission

Mary Applegate, MD MPH
November 29, 1994

Benefits

Identify HIV-exposed infants
Appropriate early care for HIV-infected infants
Prevent breast-milk transmission
Counsel mothers about future childbearing

Complexities

Mother's HIV status tested – majority of HIV+ newborns uninfected
Possible consequences of testing without consent
deter highest risk women from obtaining prenatal care
reduce cooperation with health care for infant

NOT A CLEAR IMPERATIVE — A COMPLICATED TRADE-OFF

Variables affecting trade-off

Benefits of HIV testing
? cases prevented
risk of breast-milk transmission
rate of breastfeeding if HIV status unknown
? benefit of early HIV intervention with infected infants
Costs of deterring women from prenatal care
? number deterred
only women at high risk of HIV infection – drug use, sexual risk
current rates of prenatal care utilization among high risk women
? value of prenatal care in preventing bad outcomes, e.g. low birthweight
DIGRESSION:
difficult to assess precisely because of inherent selection bias
approaches to controlling bias
greatest value for highest risk groups

HIV-LBW

MODEL: ***How large would deterrent effect have to be to counter benefits of testing?***

Explore implications of complex web of variables
Test effect of varying assumptions

OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

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

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

FACSIMILE COVER SHEET

TO: Jennifer Klein

FAX NUMBER: _____

FROM: Richard Sorian

DATE: 6/30/95

PAGES INCLUDING COVER SHEET: 5

COMMENTS:

Final draft of press release we discussed.

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Embargoed for Release
Thursday, July 6, 1995, 4 p.m.

Contact: Public Health Service
Centers for Disease Control
and Prevention
Office of Public Affairs (404) 639-3286

CDC Urges HIV Counseling and Voluntary Testing for All Pregnant Woman

The Centers for Disease Control and Prevention (CDC) published guidelines today that call upon medical professionals to offer routine HIV counseling and voluntary testing to all pregnant woman in the United States.

The U.S. Public Health Service (PHS) guidelines were developed following a National Institutes of Health (NIH) study (ACTG 076) demonstrating that pregnant women can reduce the chances of transmitting HIV to their babies by as much as two-thirds if zidovudine (ZDV or AZT) therapy is initiated at 14 weeks or as soon as possible thereafter during pregnancy, continued through labor and delivery, and provided to the newborn for the first 6 weeks of life. According to CDC, this study offers another strong reason for women to seek early prenatal care, and as part of that care, to learn their HIV status.

"We have witnessed an unprecedented breakthrough in HIV prevention," said CDC Director David Satcher, M.D, M.P.H. "Our challenge is to translate the science into action and provide for any pregnant woman who may be HIV-infected the best chance of preventing transmission to her child."

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. To achieve that, PHS

-More-

guidelines recommend routine HIV counseling and voluntary testing for all pregnant women -- a strategy that has already proven effective in several communities nationwide. In one inner-city hospital in Atlanta, Georgia, for example, 96% of women chose to be tested after being provided HIV counseling.

If women do not receive prenatal care, or if for any reason their HIV status is unknown at the time of delivery, the guidelines also recommend that they be offered HIV testing for themselves or their babies shortly after birth.

An estimated 7,000 HIV-infected women give birth in the United States each year. Absent AZT therapy, the HIV transmission rate from mother to infant is about 15-30%. Based on this transmission rate, about 1,000-2,000 HIV-infected babies are born annually.

"Ultimately the best way to prevent infection in babies is to prevent infection in women, so we must, and will, continue to focus on targeted prevention programs for women," said Helene Gayle, M.D., M.P.H., acting director of the CDC's newly established center for HIV, STD and TB prevention. "We must also reach pregnant women who are infected and give them the opportunity to improve their health and to protect their babies from perinatal transmission. To do this, we must begin by offering HIV counseling and voluntary testing to all pregnant women."

Gayle stressed, however, that counseling and testing alone cannot prevent mother-to-infant transmission. "Simply knowing a woman is infected will not prevent transmission of HIV to her baby. To reduce the chances of transmission, we must provide ongoing treatment and care, including AZT therapy." said Gayle.

Public health and medical professionals believe that voluntary testing is essential to.

establish the trusting patient-provider relationship necessary for women to make complex decisions about care for themselves and their babies and to follow through with treatment.

The U.S. Public Health Service Recommendations for HIV Counseling and Voluntary Testing for Pregnant Women are being published in the July 7, 1995, edition of the *Morbidity and Mortality Weekly Report.* CDC developed the guidelines in conjunction with federal, state, and local health agencies, health and medical organizations, and members of affected communities.

As public health and medical professionals prepare to implement the guidelines, the PHS is taking steps to ensure that they are rapidly adopted and to evaluate their effectiveness.

"To prevent the continuing toll of HIV/AIDS on women and children, we must work together to develop policies and programs that provide women both opportunities for prevention and access to needed services and care," said Gayle.

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CDC URGES ALL PREGNANT WOMEN TO TEST FOR HIV

If you are pregnant, the Centers for Disease Control and Prevention (CDC) urges you to get tested for HIV, the virus that causes AIDS. Recent medical advances from the National Institutes of Health show that if you are infected with HIV, early diagnosis and treatment with AZT may greatly reduce the chance of transmitting HIV to your baby. The AIDS virus can be passed from a mother to a newborn during pregnancy, labor and delivery, as well as through breast-feeding.

An estimated 7,000 women infected with HIV give birth every year in the United States and about 1,000-2,000 babies are born infected. With AIDS cases among women growing at about 17% a year, more babies may be at risk for HIV. However, if HIV is detected early in pregnancy and a treatment regimen with the drug AZT is followed, hundreds of HIV infections from mother to child may be prevented each year.

Because of this tremendous prevention opportunity, the Public Health Service has issued guidelines calling for medical professionals to provide routine counseling and offer voluntary HIV testing to all pregnant women. Research shows that most women choose to be tested after they discuss with their physicians the possible implications of HIV infection for themselves and their babies. If women do not know their HIV status when they go into labor, they should be offered HIV testing for themselves or their babies shortly after their baby is born.

Learning your HIV status early is important, and will allow you to receive care you may need and to make important decisions about the health of your baby.

For more information about HIV and AIDS, call the CDC's National AIDS Hotline at 1-800-342-AIDS or (Spanish Service 1-800-344-SIDA) and (Hearing Impaired Service 1-800-243-TTY).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

ISSUE SUMMARY

HIV Survey of Childbearing Women This CDC survey has been conducted since 1988 to monitor the trends of HIV infection in childbearing women, children, and indirectly, heterosexual HIV transmission. The individual identities of newborn blood samples are removed prior to HIV testing. Because the survey design is population-based with identifiers removed, and no extra blood is drawn, it has passed national and state IRB (research review boards) and a careful Institute of Medicine review. It also conforms with World Health Organization standards. Forty five States, DC, Puerto Rico and some territories participate.

ACTG 076 Findings and CDC Guidelines The results of the NIH ACTG 076 trial showed that maternal transmission of HIV could be prevented in two thirds of pregnancies when mothers received AZT during pregnancy, at delivery, and their newborns received AZT for the first 6 weeks. This is the first example of preventing HIV transmission. CDC first issued draft guidelines in February recommending all pregnant women be counseled and be encouraged to accept voluntary testing. Parents whose newborn's status is unknown should be counseled and encouraged to get their infant voluntarily tested.

The final U.S. Public Health Service Recommendations for HIV Counseling and Voluntary Testing for Pregnant Women are being released July 8, 1995 endorsing the CDC approach. These were developed over 2 years in conjunction with State and local health agencies, American Academy of Pediatrics, American College of Obstetricians and Gynecologists, other professional health care provider organizations, and members of the affected community. They have been widely endorsed.

Opportunistic Infection Guidelines Many infants with HIV infection present with pneumocystis carinii pneumonia in the first 6 months of life, a serious and sometimes fatal illness. CDC issued new guidelines in May 1995 recommending early prophylactic treatment with antibiotic for all newborns suspected of being HIV positive. To prevent pneumonia during this high-risk time, treatment should be started during the first few weeks of life.

Ackerman Legislation Cong. Gary Ackerman (D-NY) introduced legislation with co-sponsors (predominantly Democratic) to require CDC to unblind, or notify, the legal guardians of children who test HIV+. In 75% of cases, the infant will be negative, but their mothers are HIV+. There is no requirement for care to be provided to these babies. Transmission can not be prevented at this time, as mothers who choose to breastfeed will have begun this prior to test results being available. Ackerman's concern is that infants receive prophylactic therapies to prolong the length and quality of their lives.

PHS Suspension of the Survey On May 11, 1995 Dr. Phil Lee asked States to suspend the HIV Survey of Childbearing Women, until a consultative process involving States, national HIV/AIDS organizations, CDC Advisory Committee on Prevention of HIV Infection, and other interested parties could be completed. This review was merited in light of the new prevention opportunities documented by ACTG 076 and the OI guidelines. Some public health organizations are unhappy about suspending the survey during this review, while others voice ethical concerns about continuing it in its current format. A public meeting sponsored by the PHS in Atlanta will be held July 11-12, 1995 on surveillance, counseling and testing needs of women and children and linkages to systems of care.

Coburn Amendment to Ryan White CARE Act Rep. Coburn is circulating an amendment for the Huse Commerce Committee mark-up of Ryan White. This would block States from receiving their Title II funding unless the State passed a law requiring mandatory HIV screening of all newborns whose mothers were not tested during pregnancy. Each State is required to pass a law prohibiting discrimination in health insurance on the basis of HIV infection. Opposition to this amendment includes NGA, which views this as an unfunded mandate, the insurance industry, and mainstream medical groups who oppose federal mandates imposed on patient-provider relationships. The vote count is unclear.

Quick Pros and Cons of Mandatory Testing of Newborns

Pros:

* Identify 100% of children exposed to HIV, 25% of whom will develop HIV infection (1300 - 2000 infants/year)
* Identify children who need prophylactic medications against PCP pneumonia early during high risk period

Cons:

* Too little too late, doesn't prevent HIV transmission to infants and diverts focus from prenatal counseling/testing
* Federal mandate is interpreted by NGA as an unfunded state mandate
* Potential high cost to child custody systems if parents refuse newborn testing and children must be placed under State protection
* Viewed as extreme government intrusion on medical practice by groups such as the AMA, etc
* Mandatory testing is fruitless unless HIV+ children are provided follow-up treatment to improve their lives. Testing strategies must be linked to care.
* Identifies HIV+ mothers without their consent, risking their alienation from the health care system for both their own care and that of their child

PHS Two Key Responsibilities The primary goals of PHS must be:

* To prevent new HIV infection at every opportunity and reduce the morbidity associated with HIV.

* To monitor the trends of the HIV epidemic within the USA, the demographics of affected groups and modes of transmission, so that effective prevention strategies can be designed and resources for health care needs projected.

Preventing HIV Infection The most effective public health strategy we have to prevent new HIV infection in children is counseling pregnant women and offering them voluntary testing and appropriate care. Research shows that done well, over 90% of pregnant women accept HIV testing. Populations often at highest risk for HIV are often poor, engaged in substance abuse, or mistrustful of health care systems; to effectively reach these women and engage them in the necessary, and complex, treatment regimen they must follow, health providers need to engage -- not alienate -- them. A threat of mandatory testing for the mother or her baby can drive women away from care --- losing the opportunity to treat both the mother and the baby. **The CDC guidelines on counseling and testing support this voluntary approach, and their implementation is a high priority.**

Individuals concerned about the "rights of the child" need to recognize that the participation/cooperation of parents and caregivers is essential if children are to receive needed medications at home. The best way to treat a child is to involve the family. **The debate must be based in public health science, and not argued as a civil liberties issue. Rights are an abstract concept while the need for medical care necessarily involves the family.** Alienating families ruins this opportunity, unless children are removed and placed under protective custody -- a drastic move no one has proposed.

Monitoring the Epidemic Conservatives and public health groups agree that there is a critical need to have good data about the demographics of HIV across the country, if we are to contain the epidemic. There is anger among some that the CDC survey, the gold standard, has been discontinued. It is vital to act quickly to reinstate some form of monitoring tool, for both public health and political reasons. The PHS public meeting on July 11-12, 1995 will review different surveillance options and identify that which is most appropriate to support monitoring implementation of 076 guidelines as well as meeting surveillance needs. Findings from this meeting will inform PHS considerations of how best to meet surveillance needs, with a decision on new surveillance approaches to be made by early Fall.

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FACSIMILE COVER SHEET

TO: Jennifer Klein

FAX NUMBER: 456-2878

FROM: Patsy Fleming

DATE: July 5, 1995

PAGES INCLUDING COVER SHEET: 3

COMMENTS:

THE WHITE HOUSE

WASHINGTON

July 5, 1995

MEMORANDUM FOR MELANNE VERVEER AND JENNIFER KLEIN

FROM: Patsy Fleming

SUBJECT: Proposed column on HIV testing of newborns

cc: Carol Rasco

I am pleased that the First Lady wants to do a column on an AIDS-related issue. It would be valuable to use this forum to educate the American people about the real progress we have made in preventing perinatal transmission of HIV.

I am concerned, however, about the proposed focus of the column being on the issue of mandatory testing of newborns -- as opposed to emphasizing the Administration's support for a comprehensive program of prenatal counseling, testing, and services to prevent HIV infection. The latter is the real answer to pediatric AIDS and would benefit greatly from leadership from the highest levels of the Administration to be sure that we do indeed implement a comprehensive program. Injecting the issues around mandatory testing of newborns poses several policy and political issues that would make the President and his Administration vulnerable at this time.

- An early column on this subject would appear to preempt a decision-making process to which the Administration is already committed. When the CDC's seroprevalence survey of childbearing women was suspended, the Public Health Service committed to a consultation process on newborn screening, among other issues. This will be followed by recommendations from the PHS to the Secretary of HHS. That process is under way -- a public meeting is being held in Atlanta on July 11th and 12th. One of the strongest criticisms of previous administrations on AIDS issues was that politics interfered with public health. We should at least await the formal recommendations of the PHS before moving forward.

- The Administration could be vulnerable to criticism that it is focusing on a mandatory approach without having fully developed a response that would implement the guidelines on voluntary prenatal testing. Those guidelines have received wide support. We have an obligation to let people know that we are doing everything we can to implement them. We have begun that process, but frankly, we are not all the way there. For example, while HCFA has mandated that all states cover AZT therapy for infected pregnant women, we have not yet convinced HCFA to mandate coverage of the counseling and testing that would determine who needs AZT therapy in the first place.

• Endorsement of mandatory testing at this time would send a mixed message about the intentions of the government. This could actually undermine the success of voluntary prenatal testing. Many women may not understand the distinction between a policy of voluntary prenatal testing and mandatory newborn testing. The result could be that they shy away from prenatal care -- undermining our primary objective of preventing perinatal transmission. We have considerable history with confused messages. For example, after years of advertising and education campaigns, far too many Americans still believe that HIV can be transmitted through donating blood because of the publicity around transfusion-associated AIDS and the transmission of HIV through sharing needles.

• Supporting mandatory testing of newborns opens a series of questions we are not yet ready to answer. Do we mandate treatment of the newborn? Do we assure payment for that treatment? Will this be used as a threat to the custody rights of the mother? (And if so, when three-fourths of the babies turn out to be uninfected -- as they will -- what do we do then?)

• Finally, the AIDS community's response to this will be extremely negative and hostile. It is one thing to accept an amendment that requires mandatory testing on a bill that everyone wants to see signed; it is quite another to take the lead on this issue. Certainly the gay/lesbian portion of the AIDS community, which has been disappointed with the Administration's response on a number of gay/lesbian issues, would consider this a major step back from commitments made in the campaign to oppose mandatory testing. I do not doubt that as the science advances there is going to have to be a rethinking of some of our views on testing, but this may not be the time or the forum to do so. Significant consultation with the community should precede such a step.

In sum, if there is to be a column on AIDS, it is my hope that it will focus on the implementation of the voluntary prenatal testing guidelines. This is not to say that the issue of what to do about those newborns whose mothers have refused HIV testing should not be addressed. Nor is it to say that this does not pose very challenging ethical and policy questions. However, I believe at a time when this issue is the source of such confusion and hot debate, it would be better for us to focus on the positive things we can and should be doing to prevent perinatal transmission in the first place.

If I can be of any additional help on this matter, please let me know. I would be glad to discuss these concerns directly with the First Lady if you think this would be helpful.

FIRST LADY HILLARY RODHAM CLINTON
PEDIATRIC AIDS FOUNDATION PSA CAMPAIGN KICK-OFF
THE WHITE HOUSE
MAY 22, 1995

[NOTE: Acknowledgment of Stephanie Amande (almond-a) (HIV-infected mother) comes at the end.]

[Acknowledge Patsy Fleming, National AIDS Policy Coordinator.] Thank you all for coming, and thank you for the contributions you are making in the fight against pediatric AIDS. I'd like to say a special thanks to Susie Zeegan and Susan DeLaurentis for their tireless leadership of the Pediatric AIDS Foundation and of the PSA campaign we are here to unveil. I sent a letter to be read at Elizabeth's memorial service and in it I wrote that we could best honor her by continuing her mission. As many of you know so well, Susan and Susie do this everyday, and this PSA campaign is just one example of their tremendous work.

Nobody fought harder and did more in the fight against pediatric AIDS than Elizabeth Glaser. And nobody fought with more dignity and courage. When Elizabeth discovered that she had contracted HIV from a blood transfusion after the delivery of her daughter Ariel, she could have given up. When she discovered that Ariel and her son Jake, born 3 years later, had both contracted the virus, she could have given up. And when Ariel died of HIV infection at the age of 7, Elizabeth could have given up. But instead of giving in and giving up, Elizabeth channeled her energy and passion into the fight against pediatric AIDS.

The Pediatric AIDS Foundation exists because Elizabeth refused to see herself and her children as victims of fate. She lit candles of hope for children by igniting fires under Presidents, Congress, bureaucrats, scientists and doctors. She had tremendous success in mobilizing private support and in getting Republicans and Democrats to work together against AIDS. Elizabeth succeeded in part because she reminded us that everyone is at risk -- wealthy or poor, black, white, red, yellow or blue. But, more importantly, she succeeded because of her enormous tenacity, compassion and grace.

Paul has continued the fight with a strong sense of responsibility to Elizabeth -- and to other women and children who may not *have to* live with HIV and AIDS because of the work that Elizabeth and others began. Again, rather than giving in or giving up, Paul worked ceaselessly with Elizabeth, and continues their commitment to increase awareness about AIDS and raise funds for research to find treatments and a cure.

The results of Paul and Elizabeth's dedication and devotion are clear. When Elizabeth helped found the Pediatric AIDS Foundation in 1988, there was no pediatric AIDS research agenda. Since then, the Foundation has raised $31 million. It has

sponsored unique collaborations among government, businesses, and private research institutions. Its Ariel Project brought together key researchers and clinicians to find a way to block transmission from an infected mother to her newborn child.

Of course, that is why we are here today. Because finally -- as the public service announcement you see on display here today says -- there is "some good news about AIDS." As you know, last year, a study sponsored by the National Institutes of Health found that drug treatment during pregnancy will significantly reduce the risk that an HIV-infected mother will transmit the virus to her child. About 7,000 HIV-infected mothers give birth each year, and without treatment, about 25 percent of those children are born infected with HIV. This study shows that treatment can reduce the rate of transmission from 25 percent to 8 percent.

With this information comes opportunity and hope. The opportunity for women to get tested for HIV. The opportunity to get these women the treatment they need to help themselves and their babies. And the hope that with the guidance of doctors and counselors and the vigilance of mothers, we can prevent infection of newborn babies.

This is one of those times when Republicans and Democrats agree on a common goal -- that mothers should be tested for HIV so that we can save kids. We need to do everything we can to protect children who never have to become HIV-infected. And that's what this PSA campaign is all about. In cooperation with its partners in business, government, the AIDS community and the medical community, the Pediatric AIDS Foundation's campaign will reach out to give women the information and encouragement they need to protect their own health and the health of their children.

But information alone is not enough. HIV-infected women and their children must have access to health care and other support services. That's why we protect funding for the Ryan White CARE Act -- which pays for AIDS-related drugs and primary care services, including counseling and testing. That's why we need to support public health institutions like the CDC and the World Health Organization -- that are working to stop epidemics like AIDS.

And that's why we must protect the Medicaid program from the severe cuts being considered on the hill. The Medicaid program covers more than 92 percent of the children with AIDS. And the Health Care Financing Administration is working with states to assure Medicaid coverage of AZT for the prevention of perinatal transmission of HIV. We can't let budget politics threaten our ability to prevent HIV infection in babies.

The battle against pediatric AIDS is being fought every day -- by advocates like the Pediatric AIDS Foundation, by researchers and doctors, by mothers and fathers, and by so many remarkably brave and strong children. The NIH study -- and this campaign to send the message to women about the importance of getting tested -- show us that we *can* win the fight. That there can be more mothers like Stephanie Amande (almond-a), who is with us today, who take advantage of the treatments we know work, and who can give their children the chance to grow up without HIV infection.

# # #

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

FYI HRC — MAGGIE To Ian

ıbia Ignores :s by Military

Editor:

"Colombia Marvels at Drug ɔin: A Chain-Saw Killer, Too?" /s article, June 21): You miss a point when you turn to Henry ıiza Ceballos's role with the army ıd police in what has become ıown 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

THE NEW YORK TIMES, FRIDAY, JUNE 30, 1995

CDC HIV/AIDS PREVENTION

CENTERS FOR DISEASE CONTROL AND PREVENTION

Prevention Communications
Division of HIV/AIDS

FACSIMILE TRANSMISSION

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Date: 6-30-95

Number of Pages: 5
(Including this page)

Subject: (1) PRESS RELEASE (HAVEN'T RECEIVED THE FORMATTED VERSION FROM OPA YET - BUT HERE IS TEXT)

Comments:

(2) MAJIE ARTICLE

Embargoed for Release
Thursday, July 6, 1995, 5 p.m.

CDC Press Contact:

CDC Urges HIV Counseling and Voluntary Testing for All Pregnant Women

The Centers for Disease Control and Prevention (CDC) published guidelines today that call upon medical professionals to offer routine HIV counseling and voluntary testing to all pregnant women in the United States.

The U.S. Public Health Service (PHS) guidelines were developed in the wake of a National Institutes of Health (NIH) study (ACTG 076) demonstrating that pregnant women can reduce the chances of transmitting HIV to their babies by as much as two-thirds if zidovudine (ZDV or AZT) therapy is initiated early in pregnancy, continued through labor and delivery, and provided to the child for the first 6 weeks of life. According to CDC, this study offers another strong reason for women to seek early prenatal care, and as part of that care, to learn their HIV status.

"We have witnessed an unprecedented breakthrough in HIV prevention," said CDC Director David Satcher, M.D, M.P.H. "Our challenge is to translate the science into action and provide for any pregnant woman who may be HIV-infected the best chance of preventing transmission to her child."

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. To achieve that, PHS guidelines recommend routine HIV counseling and voluntary testing for all pregnant women -- a strategy that has already proven effective in several communities nationwide. In one inner-city hospital in Atlanta, Georgia, for example, 96% of women chose to be tested after being provided HIV counseling.

If women do not receive prenatal care, or if for any reason their HIV status is unknown, the guidelines also recommend that HIV testing be offered to the mothers or

their babies at or shortly after labor and delivery.

An estimated 7,000 HIV-infected women give birth in the United States each year. Assuming an HIV transmission rate from mother to infant of about 15-30% without therapy, about 1,000-2,000 HIV-infected babies are born annually. Moreover, AIDS cases among women are growing at about 17% a year -- nearly 6 times the rate for the population overall.

"Ultimately the best way to prevent infection in babies is to prevent infection in women, and we must continue to focus on targeted prevention programs for women," said Helene Gayle, M.D., M.P.H., acting director of the CDC's newly established center for HIV, STD, and TB prevention. "We must also reach pregnant women who are infected and give them the opportunity to improve their health and that of their babies. To do this, we must begin by offering HIV counseling and voluntary testing to all pregnant women."

Gayle stressed, however, that counseling and testing alone cannot prevent mother-to-infant transmission. "Simply knowing a woman is infected will not prevent her from transmitting HIV to her baby. To reduce the chances of transmission, we must provide ongoing treatment and care." said Curran.

Public health and medical professionals believe that voluntary testing is essential to establish the trusting patient-provider relationship needed for women to make complex decisions about care for themselves and their babies and to follow through with treatment.

The U.S. Public Health Service Recommendations for HIV Counseling and Voluntary Testing for Pregnant Women are being published in the July 7, 1995, edition of the *Morbidity and Mortality Weekly Report.* CDC developed the guidelines in conjunction with federal, state, and local health agencies, health and medical organizations, and

members of the affected community.

As public health and medical professionals prepare to implement the guidelines, the PHS is taking steps to ensure that they are rapidly adopted and to evaluate their effectiveness.

"To prevent the continuing toll of HIV/AIDS on women and children, we must work together to develop policies and programs that provide women both opportunities for prevention and access to needed services and care," said Gayle.

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CDC URGES ALL PREGNANT WOMEN TO TEST FOR HIV

If you are pregnant, the Centers for Disease Control and Prevention (CDC) urges you to get tested for HIV, the virus that causes AIDS. Recent medical advances from the National Institutes of Health show that if you are infected with HIV, early diagnosis and treatment may greatly reduce the chance of transmitting HIV to your baby. The AIDS virus can be passed from a mother to a newborn during pregnancy, labor and delivery, as well as through breast-feeding.

An estimated 7,000 women infected with HIV give birth every year in the United States and about 1,000-2,000 babies are born infected. With AIDS cases among women growing at about 17% a year, more babies may be at risk for HIV. However, if HIV is detected early in pregnancy and a treatment regimen with the drug AZT is followed, hundreds of HIV infections from mother to child may be prevented each year.

Because of this tremendous prevention opportunity, the Public Health Service has issued guidelines calling for medical professionals to provide routine counseling and offer voluntary HIV testing to all pregnant women. Research shows that most women choose to be tested after they discuss with their physicians the possible implications of HIV infection for themselves and their babies. If women do not know their HIV status when they go into labor, they should be offered HIV testing at or shortly after labor and delivery.

Learning your HIV status early is important, and will allow you to receive care you may need and to make important decisions about the health of your baby.

For more information about HIV and AIDS, call the CDC's National AIDS Hotline at 1-800-342-AIDS or (Spanish Service 1-800-344-SIDA) and (Hearing Impaired Service 1-800-243-TTY).

Estimated cost of mandatory testing of newborns whose mother's status is unknown:

Assumptions:

- 4.2 million live births annually
- Cost of testing ranges from $5 to $33 ($5=the cost of the test alone; $33 is the cost of counseling and testing at a publicly funded site)
- What few studies we have show a range of 75% to 96% of voluntary prenatal testing; thus the range of newborns that would need to be tested is 4% to 25% (or 168,000 to 1,050,000). *Note:* These studies are at sites that have counseling programs in place. We have no idea what the rate of offering HIV testing is in prenatal settings and what the rate of acceptance is at the typical prenatal site.

Costs:

Low end ($5 x 168,000) = $840,000
High end ($33 x 1,050,000) = $34,650,000

Jen — This is very rough —

Coburn estimate
400,000 kids x $9 per test = $3.6 Million
↓
10% of 4 million
birth cohort

How many women get 2 consecutive prenatal visits?

Figure 1. Male adult/adolescent AIDS annual ra per 100,000 popul lion, for cases reported in 1994, United States

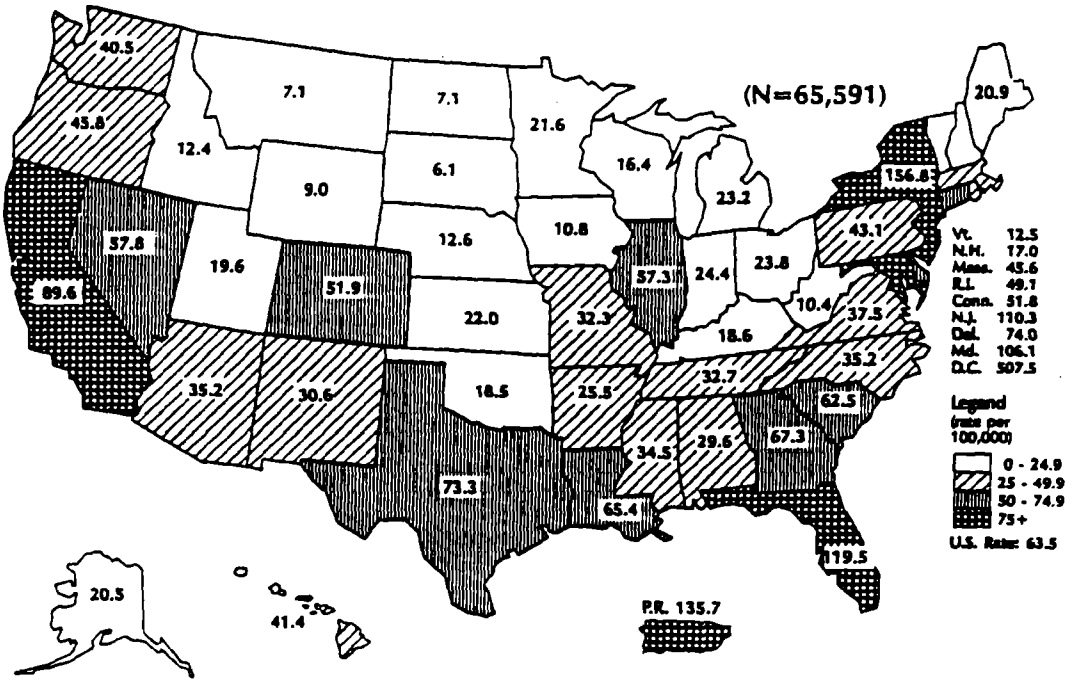


Figure 2. Female adult/adolescent AIDS annual rates per 100,000 population, for cases reported in 1994, United States

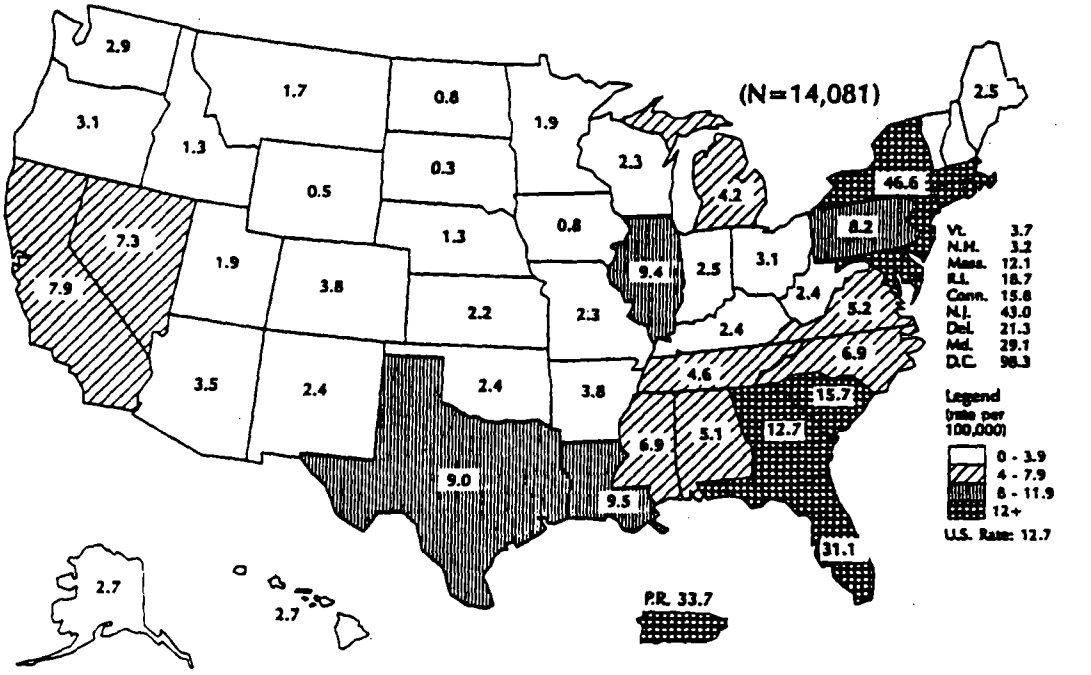


Figure 5. Pediatric AIDS cases reported in 1994, United States

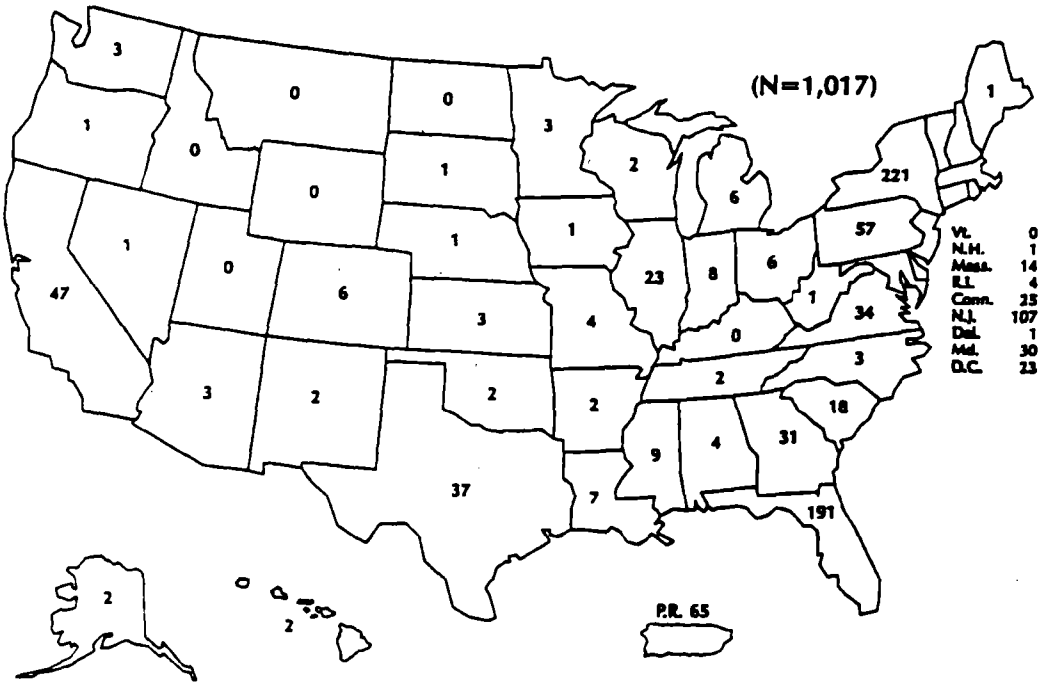
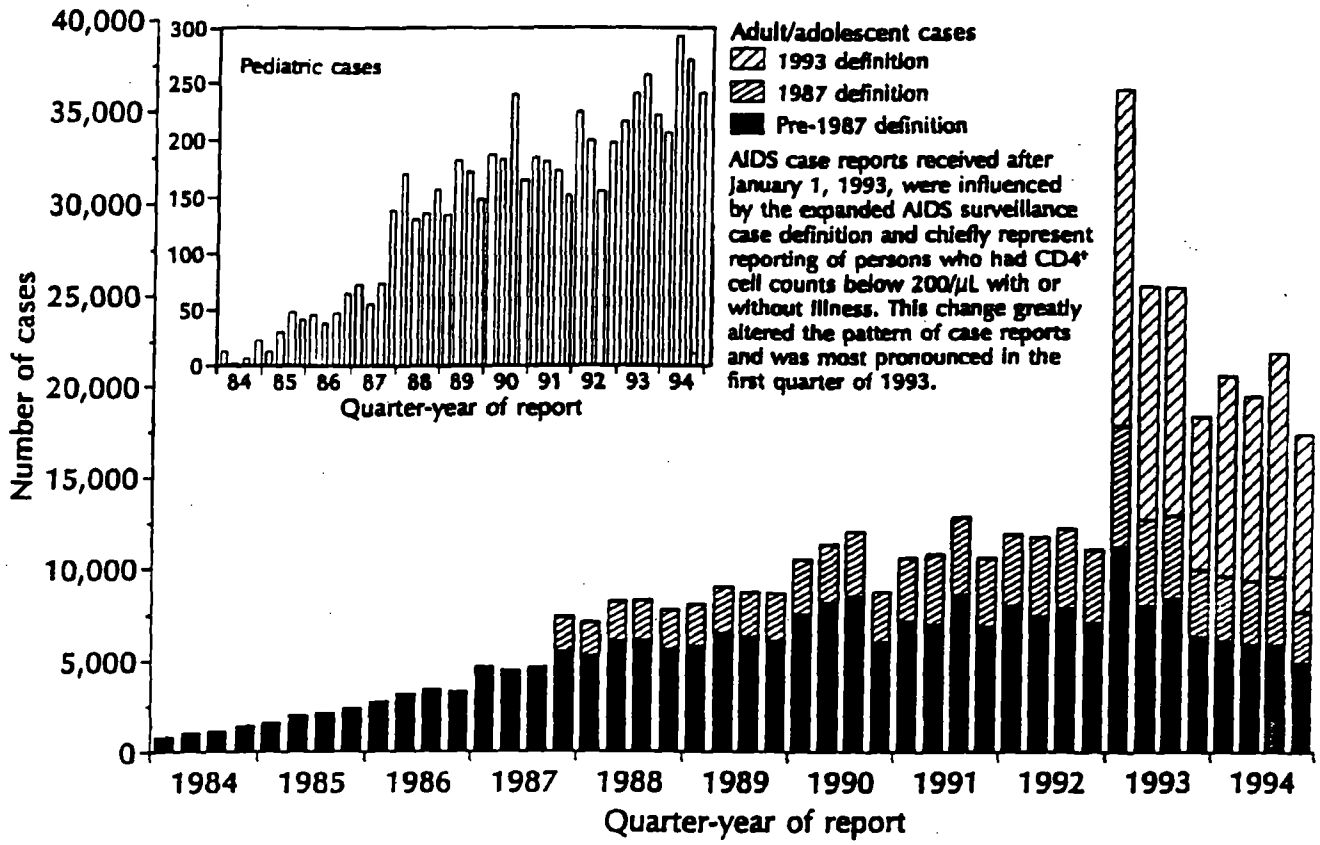


Figure 6. AIDS cases by quarter-year of report and definition category, reported 1984 through 1994, United States



HCFA does not know how many states are covering HIV testing — they are doing a survey. It is their view that they cannot mandate HIV testing. —

1/3 of births are covered by Medicaid.

QUESTIONS AND ANSWERS:

HCFA COVERAGE OF HIV SCREENING AND TESTING FOR PREGNANT WOMEN

Must States make HIV testing and counseling available to all Medicaid eligible individuals?

Medicaid law requires States to provide for coverage of certain broad categories of services such as, inpatient and outpatient hospital services, physician services, other laboratory and X-ray services, etc. Where HIV testing is related to symptoms present in a patient, we believe States are required to cover HIV testing and counseling under one of those service categories.

The law also permits, at State option, coverage of other services like clinic, preventive and screening services. In cases where HIV testing is purely preventive or screening, States are allowed to cover HIV testing (with matching federal payments) if they wish.

How are States making HIV testing and counseling services available to Medicaid eligible individuals?

States are likely covering such services under various Medicaid service categories, such as:

- Mandatory services (all States)
  - Outpatient hospital services
  - Laboratory services
  - Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services
  - Family planning services
  - Physician services
- Optional services
  - Clinic services (51 States, including District of Columbia)
  - Screening services (32 States)

Are any State Medicaid programs denying beneficiaries HIV screening and counseling services?

We are not aware of any States denying beneficiaries these services.

Are there any special Medicaid rules applicable to pregnant women or to children?

Yes. The law provides that States make available to pregnant women services which are not otherwise covered under the Medicaid program. If a State chooses, it could include routine coverage of HIV testing and counseling as part of its enhanced package of services available to pregnant women.

With regard to Medicaid eligible children under 21, the law requires States to provide a benefit known as Early and Periodic Screening, Diagnostic and Treatment (EPSDT) services. Under EPSDT, States must make screening services available, which include comprehensive health and developmental assessments. Although there is no specific requirement for HIV testing and counseling services, physicians and other health practitioners providing EPSDT services may use their clinical judgement in determining the extent of services needed.

How many pregnant women obtain HIV screening and counseling services through Medicaid?

Our data show that approximately 665,000 caretaker and pregnant women received Medicaid services in fiscal year 1993. (Caretaker women are women who are eligible for Medicaid because they care for Medicaid eligible children. Some of these women may themselves be pregnant.) HIV screening and counseling is available to all these women at the discretion of their physicians. We hope that the publication of CDC's guidelines will make physicians even more attuned to the specific medical needs of pregnant women who may be HIV+.

The number of pregnant women who specifically received HIV screening and counseling services is difficult to obtain for two reasons. First, Medicaid service data is not reported to that level of detail. We know how many women get care, but we don't know the specifics of each care visit. Second, beneficiaries may receive HIV screening and counseling services from non-Medicaid providers, including anonymous HIV testing sites and Ryan White-funded programs.

How much does Medicaid pay for HIV screening and counseling for pregnant women?

We don't know. We do know that Medicaid (Federal and State funds combined) paid nearly $2.5 billion for medical services in fiscal year 1993 on behalf of eligible caretaker and pregnant women. Without a doubt, this included HIV screening and counseling services for women in cases where the physician thought screening/counseling was indicated.