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File Type: Loose Files
File Size: Letter
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- Immunization
- AIDS
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E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

11-May-1995 09:19am

TO: Carol H. Rasco
TO: Jeremy D. Benami

FROM: Jeffrey Levi
AIDS Policy Council

CC: Jennifer L. Klein

SUBJECT: Mandatory testing hearing

At today's House health subcommittee hearing on mandatory HIV testing for pregnant women and newborns, the PHS will announce that they are asking states to suspend the Survey of Childbearing Women pending consultation with the CDC Advisory Committee on AIDS and outside experts -- and will ask that states divert resources spent on the survey to counseling and testing of pregnant women.

This is good news -- it took quite some time to convince CDC to accept the realities of the situation. By removing the survey from the table it will now be possible to focus debate on the more central question of mandatory testing. The CDC statement for the hearing is a strong argument against mandatory testing.

TESTIMONY

of

Charles M. van der Horst, MD

Associate Professor of Medicine at the University of North Carolina at Chapel Hill

Director/Principal Investigator of the AIDS Clinical Trials Unit at UNCCCH

11 May, 1995

I am honored at the invitation to appear before you. I come before you as an internist and an infectious diseases specialist who has taken care of people infected with HIV since 1981. I am the principal investigator of two NIH funded grants to study new procedures for treating people with HIV. In addition to my research, I have an active clinical practice. In our clinic we follow over 1,000 people infected with HIV, over one third of whom are women.

The testing of pregnant women for HIV is an issue about which people have strongly held and often differing views. Some see their position as absolute and clear and one is either for it or against it. When I reflect on my years of caring for women and infants, however, I am compelled to see the issue as more complex than it appears.

I like to think of the two sides of this issue as balanced on a scale. On one side are the lives of babies, a powerful image. We know that each year there will be approximately 7000 babies born nationwide to women infected with HIV (*MMWR*, Vol. 44, p. 81-84, 2/10/95, figures for 1993). One quarter of those babies, or 1750, will be infected with HIV and die. If the women took AZT before delivery and if their newborns took it after delivery as well, only 580 of those 7000 babies would be infected. Thus, more than 1100 lives would be saved.

On the other side of the scale are the important rights of the pregnant women. If we do not respect the rights of women in this most intimate of matters, we will actively discourage them from seeking testing and care, and we will encourage psychological denial instead of participation in programs that can help them and their families. The decision to take AZT during pregnancy is a complex one and should take into account what is in the best interests of her own health as well as that of her fetus.

Again, we need to remember the reality of what it means to provide medical care for these women and their children. We, as their health care givers, must remember the difficult worlds in which they live. Above all, our policies have to be practical. It is one thing to make policy statements about what we might like to see happen, but policies need to work in the real world. Simply legislating the testing of women will not save the 1100 babies unless we provide for prenatal visits, no cost AZT administration to mothers and their infants, and follow-up clinic visits. We are dealing with a world of people where there is already an endemic mistrust of the health care system. We are talking about a world where there is also a profound shortage of support services. This often means that women simply cannot participate successfully in treatment regimens even when they want to because of lack of housing, transportation, and adequate day-care. If you pass a law mandating testing, then to make use of the test results you must also appropriate the funds to expand the services that make testing possible.

The complexity of how people feel was brought home dramatically to me by one woman, a mother of two children. Both she and her husband were HIV positive and she was visiting our clinic for the first time. She was a well dressed, handsome woman, articulate and calm about her condition. I asked her about her family, and urged her to persuade her husband to come in for treatment. I suggested that we should test her children. She quietly shook her head, a firm expression on her face. This was obviously something she had thought long and hard about. I was puzzled and explained to her that if her children were infected, we could treat them so that they could live longer and have more productive lives. She still shook her head and said she did not move down to North Carolina to put her children through that. From the ivory tower where I sit, her reaction made no sense. What parent would not want the best for their children: diagnosis and treatment for any terrible disease that might afflict them?

So I got tough. I told her that even if she did not want to, North Carolina law permitted me to test her children without her consent (a true but ridiculous statement, as her children were home and I was not going to send the police to get them). At that point, still shaking her head, tears started to run down her face. She did not sob or cry out. She started gathering her bag and coat and stood to leave.

Now I had not only lost the mother, but all chance of getting the two children in for testing and the husband in for treatment. Finally, I asked her to tell me why. She was too upset to tell me, but I finally figured it out. I told her she could get her children tested anonymously so that no one would know. At that she sat back down and the interview and exam continued. She subsequently took her children in for testing, both of whom were HIV negative.

As I think about this issue, I try to be practical. How can we insure that the greatest number of pregnant women get tested, into treatment, and stop the spread of HIV?

The key ingredient missing from all of the emotional debate is the issue of trust. How can we generate trust between the medical establishment and these women and still make sure physicians do their job and offer testing? One way would be to make HIV testing a routine part of prenatal care offered to all women the same way we now test for syphilis, gonorrhea, Chlamydia, hepatitis B, and other sexually transmitted diseases. All of these infections, as well as HIV, can wreak havoc on babies. Testing, however, must be done in a non-threatening manner for doctors to retain the trust of their patients. Women must have the option of refusing testing, or we risk losing the mother, the fetus, and possibly the rest of the family.

All of this must be offered in the context of adequate and available prenatal care and delivery. Testing can not be treated as an isolated issue. Slips of paper that say "positive" or "negative" are worthless without follow-up care for those who test positive for HIV.

So how do we do what we all want to do for the mothers and their infants? I recommend the following steps:

1. **Make counseling and testing about HIV prenatal transmission routine for all pregnant women as recommended by the US Public Health Service Task Force in August, 1994. Give women the information that they need to make informed decisions about their health and the health of their children, including HIV testing, in a non-coercive manner.**
2. **Provide a major increase in the Ryan White CARE Act and HOPWA funding in order to help us reduce, not raise, the barriers to receiving care for mothers and their infants. Please remember that we will do better by pulling women into care than pushing them toward it. We draw women towards health care by offering more services and support, not by chasing after them with a mandatory testing law.**
3. **Anonymous testing should be available to individuals who are too frightened of the medical establishment to come in for testing.**

Thank you for the opportunity to speak.

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TESTIMONY
BEFORE
THE HOUSE COMMITTEE
ON COMMERCE
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

May 11, 1995

Submitted by

Helene D. Gayle, M.D., M.P.H.

CDC Associate Director/ Washington
Acting Director, National Center for Prevention Services

Centers for Disease Control and Prevention

U.S. Public Health Service

Department of Health and Human Services

Mr. Chairman, members of the Subcommittee, I am Dr. Helene Gayle, Associate Director for the Washington Office of the Centers for Disease Control and Prevention (CDC) and Acting Director for CDC's National Center for Prevention Services, which is currently being reorganized to merge the HIV/AIDS, sexually transmitted disease, and tuberculosis programs. I am honored to have the opportunity to comment on HIV/AIDS prevention efforts from the perspective of CDC.

CDC, the nation's prevention agency, has primary responsibility for federal HIV prevention programs. These HIV prevention programs were initially developed during the 1980s to respond to the emerging HIV/AIDS epidemic. They have evolved, based on better scientific data and an increased understanding of the disease, to include financial and technical support for State and local health department programs (the largest component of CDC's HIV prevention efforts); direct funding of community-based organizations; funding for national and regional minority organizations; a national public information and behavior change program; funding and technical support for education programs in the nation's schools; and the traditional epidemiologic, behavioral, and laboratory studies.

Experience has taught us that at the very center of all effective HIV prevention programs is information. Information that helps us target specific individuals at risk of illness,

information that helps us to understand attitudes and behaviors, and--most important--information that helps us set priorities. AIDS case surveillance and HIV serosurveillance have provided the basis for understanding the scope and nature of the epidemic, and continue to tell us much about trends in the HIV epidemic and effectiveness of prevention interventions to help us stop it.

Today, we will be talking about a highly complex prevention issue--HIV screening policies for pregnant women and infants. This is not only a complex issue, but it is one of vital importance.

Today, there is much we can do to make perinatal prevention a reality in the majority of cases. A study led by the National Institutes of Health last year demonstrated that pregnant women with HIV infection can reduce the chances of transmitting HIV to their babies by as much as two-thirds with zidovudine (AZT) treatment. With this prevention breakthrough, we can actually save babies' lives by preventing most maternal-to-child HIV infections. Today, babies have improved chances to be born free from HIV infection and improved chances to stay healthy. To take advantage of this prevention opportunity, we must detect HIV infection as early in pregnancy as possible, and certainly long before the birth of the child.

I believe we have a common goal in this discussion, which is

to find the most effective ways to prevent infants from acquiring HIV and to give them a healthy start. To achieve this goal, we believe that CDC's responsibilities are clear:

First, the best way to prevent HIV infection in babies is to have a comprehensive strategy to prevent infection in adults-- including infection among women. We must not only prevent transmission of HIV from women to their newborns, but also prevent transmission among adolescents and adults. CDC has numerous prevention programs and activities that are directed to adolescent and adult women. Data collected from monitoring the HIV epidemic enable us to target our prevention knowledge, strategies, and resources to those who are at greatest risk of infection.

HIV prevention is really about information and behavior change: teaching individuals to stop engaging in risky behaviors and then supporting them in those changes. By definition, this must occur before individuals are infected.

It is CDC's view--and that of our partners in the public health and AIDS communities--that HIV counseling and testing is NOT the centerpiece of our prevention strategy. Testing and identifying people with HIV is not prevention. Testing is only a bridge between prevention and services. For uninformed individuals, counseling and testing is an opportunity to

reinforce prevention messages and link them to prevention services. For the HIV positive individual, this is the opportunity to get into early care--to prevent some of the opportunistic infections associated with HIV and prolong the quality and length of his or her life. For women of childbearing age, this information is important for making decisions about whether to become pregnant--or, if already pregnant, learning about therapies which might prevent the transmission of HIV to their newborn.

Therefore, testing alone is not a prevention strategy. Comprehensive prevention programs, with counseling and voluntary testing linked to care as an important element, will accomplish our goal.

CDC's second responsibility, which is equally important, is to implement and evaluate prevention strategies that can save babies' lives, even when their mothers are infected with HIV. We owe it to the approximately 7,000 HIV-infected women who have babies each year to provide them the best opportunity to protect their babies from the illness they themselves must face. This requires detection of the mother's infection as a first step, followed by a continued partnership between the health care provider and infected woman regarding appropriate therapies to minimize transmission. In response to the prevention breakthrough offered by AZT therapy, CDC has drafted guidelines

for health care professionals recommending routine counseling and voluntary testing for all pregnant women. The guidelines were developed with the advice of academic experts, clinical practitioners, public health experts, community members and advocacy organizations, based on the best scientific information available.

Among the key recommendations of CDC's proposed guidelines are:

- Health care providers should ensure that all pregnant women are routinely counseled and encouraged to be tested for HIV infection. This allows women to know their infection status both for their own health and to take measures to reduce the risk of transmission to their infants and others.
- HIV testing should be voluntary. We firmly believe that this is the most effective means of assuring the largest number of pregnant women are tested. It is also the best public health strategy to increase a mother and child's interaction with the health care system so that appropriate therapies are received.
- Health care providers should counsel and offer HIV testing to women as early in pregnancy as possible so that an informed decision regarding health care can be made in a

timely manner. Ideally, women should know their HIV status before becoming pregnant. It is also the best public health strategy to increase a mother and child's interaction with the health care system so that appropriate therapies are received.

- If for any reason the mother's status is not known, she should be given the opportunity and encouraged to allow the child to be tested at birth.

These guidelines were issued for public comment in mid-February; comments received have been reviewed and the guidelines are currently being finalized by CDC. Fully implementing these guidelines will maximize the opportunity to prevent HIV infection in newborns. Implementation should also result in the vast majority of those infants who are exposed to HIV being identified and treated in a timely matter.

CDC has also recently published "1995 Revised Guidelines for Prophylaxis Against *Pneumocystis carinii* Pneumonia (PCP) for Children Infected with or Perinatally Exposed to HIV." The PCP guidelines, originally issued in 1991, were revised in response to recent studies showing that PCP remains a common and often fatal disease in children infected with HIV--especially infants 3-6 months old. Research has shown that the most important reason PCP has not declined is that many HIV-infected children

have not been identified early enough to start preventive medication. The revised PCP guidelines stress the need to identify infants exposed to HIV as early as possible, so that therapy can be started before they are at risk for PCP. And, again, the best way to identify infants in need of care is to diagnose HIV infection voluntarily among women before or during pregnancy. Fully implemented, the counseling and testing guidelines and the PCP guidelines will combine to give children the best chance to be born healthy and free of HIV and to improve the chances for children who are infected to live longer, healthier lives.

Some have suggested that prenatal and newborn testing must be mandatory to identify HIV-infected mothers and infants and prevent HIV transmission. There is consensus among CDC, medical groups, and public health experts that offering all pregnant women HIV counseling and voluntary HIV testing is the most effective public health strategy to identify women and children in need of care and to ensure that a trusting partnership is developed between the health care provider and patient. It is critical to remember that children with HIV infection need a medical regimen that is complex and demanding, and ensuring the cooperation of the child's caregivers is an essential step in successfully providing needed therapies. A voluntary approach best protects the interests of the child in receiving important treatment. In fact, the American Academy of Pediatrics and the

Age of Obstetricians and Gynecologists have adopted recommendations. We anticipate that this voluntary approach will become standard medical practice in the United States.

Most women, after talking with their health care provider about what a test means for them and their baby, will choose to be tested and treated. As a physician, I know that a trusting relationship between provider and patient is clearly the best way to ensure that patients get the care and treatment they need and comply with their doctor's recommendations. Faced with the prospect of mandatory testing, some women may shun medical care, because of fears about discrimination; loss of jobs, housing, insurance, relationships, and children. Furthermore, testing alone will not mandate adequate follow-up care, treatment, and other services. CDC recommends HIV counseling and voluntary testing, because this strategy has proven to be effective in getting women tested and treated in several communities nationwide, including Los Angeles, Atlanta, and Baltimore. At one inner-city hospital in Atlanta, for example, 96 percent of women chose to be tested after receiving HIV counseling and being offered a voluntary test as part of prenatal care. Compliance with routine counseling by physicians and acceptance of HIV testing by pregnant women is likely to greatly increase during the next year as a result of guidelines from PHS and professional organizations, which recommend it as a standard of practice.

It is important to remember that while HIV testing during pregnancy is a crucial step, it is not by itself the intervention. This important intervention will likely be most successful when it begins with an informed patient and a trusted provider. Voluntary testing accomplishes this; mandatory testing does not, and may actually reduce the chance a woman and her baby will receive needed therapies if they are alienated from the health care system.

I'd like to take just a few moments to discuss HIV testing of infants and what it can and cannot tell us. In most cases, mother-to-infant, or perinatal, transmission occurs during pregnancy or childbirth, although it is not possible to predict when transmission will occur for individual women and their children. Rarely, HIV has been transmitted through breast feeding.

However, not every infant born to an infected woman will be infected and subsequently develop AIDS. Studies have shown that a baby born to an infected woman has a 20 to 30 percent chance of being infected with HIV. Most infants born to infected mothers are NOT infected.

While only a fraction of babies are infected, all babies born to infected mothers will have a positive HIV antibody test at birth, which reflects the presence of the mother's antibodies.

surveillanc activities, which I mentioned earlier, particularly the HIV Survey of Childbearing Women. CDC's HIV Survey of Childbearing Women was developed in 1987 because it was clear that reporting AIDS cases alone, which reflects infections that occurred years earlier, would not provide a complete picture of the extent of the epidemic, including the epidemic among women. The goal of the survey has been to track HIV infection in women to provide information for planning health care resources, and to better target and evaluate services and care to two groups increasingly affected by HIV--women and children.

Forty-five states, as well as the District of Columbia, Puerto Rico, and the Virgin Islands, have participated in the survey. Funding with grants provided to the states by CDC

provides "blinded" testing of 25 to 100 percent of specimens from newborns in a given state. Many states also provide support to supplement CDC's funding.

This survey has provided an important resource at the federal, state and community levels to develop and prioritize prevention programs, identify trends of HIV infection among women and children, and to project the need for, and costs of, health care services to care for HIV positive children and their affected parents. At the national level, the Public Health Service and professional groups have used survey data to assist in developing guidelines and recommendations, including the recommendations for HIV counseling and voluntary testing for pregnant women and their infants, and guidelines for PCP prophylaxis in children which I discussed earlier.

Today, with the recent advances in our ability to decrease perinatal transmission and slow the course of the HIV epidemic, and knowledge of the importance of early PCP prophylactic therapy for children with HIV infection, the CDC is re-evaluating how best to combine prevention and surveillance strategies to meet these important challenges. Implementation of the proposed CDC guidelines for counseling and voluntary testing of women and their infants must be a top/high priority as lives may be saved and suffering averted. Dr. Phil Lee, Assistant Secretary for Health has asked all States to immediately suspend the current

survey and, to the extent possible, dedicate remaining federal resources to implementation of the CDC guidelines.

Under the auspices of the CDC Advisory Committee on the Prevention of HIV Infection, we will convene a panel of outside experts to examine strategies to promote, implement, and evaluate in all States the CDC guidelines for counseling and testing of pregnant women and their infants and encourage the use of zidovudine to reduce the risk of perinatal transmission of HIV. Consultation with State public health officials, private providers, medical and ethical experts, providers caring for women and children with HIV disease, and communities affected by HIV will be most helpful to ensuring widespread acceptance and implementation of these guidelines. CDC is confident that its dual missions of prevention and monitoring the trends of the HIV epidemic can be fulfilled through a thoughtful public health strategy to implement the guidelines and evaluate their effectiveness.

In closing, I would like to say that we must keep our eye on our common goal of preventing HIV infection in women and children. We must also evaluate how effective our efforts are, including effective monitoring of HIV infection in women and children.

Mr. Chairman, thank you for this opportunity to discuss CDC's prevention activities and to share some of our thoughts on

this important and complex issue. This concludes my testimony.

I will be happy to answer any questions that you or other subcommittee members may have. Thank you.



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TESTIMONY
BEFORE
THE HOUSE COMMITTEE
ON COMMERCE
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

May 11, 1995

Submitted by
Helene D. Gayle, M.D., M.P.H.
CDC Associate Director/ Washington
Acting Director, National Center for Prevention Services
Centers for Disease Control and Prevention
U.S. Public Health Service
Department of Health and Human Services

Mr. Chairman, members of the Subcommittee, I am Dr. Helene Gayle, Associate Director for Washington Centers for Disease Control and Prevention (CDC) and Acting Director for CDC's National Center for Prevention Services, which houses our HIV prevention efforts. I am honored to have the opportunity to comment on HIV testing for women and children in the context of our HIV prevention efforts.

CDC, the nation's prevention agency, has primary responsibility for federal HIV prevention programs. These HIV prevention programs were initially developed during the 1980s to respond to the emerging HIV/AIDS epidemic. They have evolved, based on better scientific data and an increased understanding of the disease, to include financial and technical support for State and local health department programs (the largest component of CDC's HIV prevention efforts); direct funding of community-based organizations; funding for national and regional minority organizations; a national public information and behavior change program; funding and technical support for education programs in the nation's schools; and the traditional epidemiologic, behavioral, and laboratory studies.

Experience has taught us that at the very center of all effective HIV prevention programs is information. Information that helps us target specific individuals at highest risk of acquiring HIV infection, information that helps us to understand

attitudes and behaviors that place people at risk , and information that helps us set priorities. Collecting information on numbers of persons with AIDS and HIV infection has provided the basis for understanding the scope and nature of the epidemic, and continue to tell us much about trends in the HIV epidemic and effectiveness of prevention interventions to help us stop it.

Today, we will be talking about a highly complex prevention issue--HIV screening policies for pregnant women and infants. This is not only a complex issue, but it is one of vital importance.

Today, there is much we can do to make perinatal prevention a reality in the majority of cases. A study led by the National Institutes of Health last year demonstrated that pregnant women with HIV infection can reduce the chances of transmitting HIV to their babies by as much as two-thirds with zidovudine (AZT) treatment. With this prevention breakthrough, we can actually save babies' lives by preventing most maternal-to-child HIV infections. Today, babies have improved chances to be born free from HIV infection and improved chances to stay healthy. To take advantage of this prevention opportunity, we must detect HIV infection as early in pregnancy as possible, and certainly long before the birth of the child.

I believe we have a common goal in this discussion, which is

to find the most effective ways to prevent infants from acquiring HIV and to give them a healthy start. To achieve this goal, we believe that CDC's responsibilities are clear:

Our first responsibility and best way to prevent HIV infection in babies is to have a comprehensive strategy to prevent infection in adults-- especially women. We must not only prevent transmission of HIV from women to their newborns, but also prevent transmission among adolescents and adults. CDC has numerous prevention programs and activities that are directed to adolescent and adult women. Data collected from monitoring the HIV epidemic enable us to target our prevention knowledge, strategies, and resources to those who are at greatest risk of infection.

HIV prevention is really about providing appropriate information and behavior change: teaching individuals to stop engaging in risky behaviors and then supporting them in those changes. By definition, this must occur before individuals are infected.

It is CDC's view--and that of our partners in the public health and AIDS communities--that HIV counseling and testing is NOT the centerpiece of our prevention strategy. Testing and identifying people with HIV is not prevention. Testing is only a bridge between prevention and services. For uninfected

individuals, counseling and testing is an opportunity to reinforce prevention messages and link them to prevention services. For the HIV positive individual, this is the opportunity to get into early care--to prevent some of the opportunistic infections associated with HIV and prolong the quality and length of his or her life. For women of childbearing age, this information is important for making decisions about whether to become pregnant--or, if already pregnant, learning about therapies which might prevent the transmission of HIV to their newborn.

Therefore, testing alone is not a prevention strategy. Comprehensive prevention programs, with counseling and voluntary testing linked to care as an important element, will accomplish our goal.

CDC's second responsibility, which is equally important, is to implement and evaluate prevention strategies that can save babies' lives, even when their mothers are infected with HIV. We owe it to the almost 7,000 HIV-infected women who have babies each year to provide them the best opportunity to protect their babies from the illness they themselves must face. This requires detection of the mother's infection as a first step, followed by a continued partnership between the health care provider and infected woman regarding appropriate therapies to minimize transmission. In response to the prevention breakthrough offered

by AZT therapy, CDC has drafted guidelines for health care professionals recommending routine counseling and voluntary testing for all pregnant women. The guidelines were developed with the advice of academic experts, clinical practitioners, public health experts, community members and advocacy organizations, based on the best scientific information available.

Among the key recommendations of CDC's proposed guidelines are:

- Health care providers should ensure that all pregnant women are routinely counseled and encouraged to be tested for HIV infection. This allows women to know their infection status both for their own health and to take measures to reduce the risk of transmission to their infants and others.
- HIV testing should be voluntary. We firmly believe that this is the most effective means of assuring the largest number of pregnant women are tested. It is also the best public health strategy to increase a mother and child's interaction with the health care system so that appropriate therapies are received.
- Health care providers should counsel and offer HIV testing to women as early in pregnancy as possible so that an

informed decision regarding health care can be made in a timely manner. Ideally, women should know their HIV status before becoming pregnant. It is also the best public health strategy to increase a mother and child's interaction with the health care system so that appropriate therapies are received.

- If for any reason the mother's status is not known, she should be given the opportunity and encouraged to allow the child to be tested at birth.

These guidelines were issued for public comment in mid-February; comments received have been reviewed and the guidelines are currently being finalized by CDC. Fully implementing these guidelines will maximize the opportunity to prevent HIV infection in newborns. Implementation should also result in the vast majority of those infants who are exposed to HIV being identified and treated in a timely matter.

CDC has also recently published "1995 Revised Guidelines for Prophylaxis Against *Pneumocystis carinii* Pneumonia (PCP) for Children Infected with or Perinatally Exposed to HIV." The PCP guidelines, originally issued in 1991, were revised in response to recent studies showing that PCP remains a common and often fatal disease in children infected with HIV--especially infants 3-6 months old. Research has shown that the most important

reason PCP has not declined is that many HIV-infected children have not been identified early enough to start preventive medication. The revised PCP guidelines stress the need to identify infants exposed to HIV as early as possible, so that therapy can be started before they are at risk for PCP. And, again, the best way to be aware of infants in need of care is to diagnose HIV infection voluntarily among women before or during pregnancy. Fully implemented, the counseling and testing guidelines and the PCP guidelines will combine to give children the best chance to be born healthy and free of HIV and to improve the chances for children who are infected to live longer, healthier lives.

Some have suggested that prenatal and newborn testing must be mandatory to identify HIV-infected mothers and infants and prevent HIV transmission. There is consensus among CDC, most medical groups, and public health experts that offering all pregnant women HIV counseling and voluntary HIV testing is the most effective public health strategy to identify women and children in need of care and to ensure that a trusting partnership is developed between the health care provider and patient. It is critical to remember that children with HIV infection need a medical regimen that is complex and demanding, and ensuring the cooperation of the child's caregivers is an essential step in successfully providing needed therapies. A voluntary approach best protects the interests of the child in

receiving important treatment. We anticipate that this routine counseling and voluntary approach will become standard medical practice in the United States.

Most women, after talking with their health care provider about what a test means for them and their baby, will choose to be tested and treated. As a physician, I know that a trusting relationship between provider and patient is clearly the best way to ensure that patients get the care and treatment they need and comply with their doctor's recommendations. Faced with the prospect of mandatory testing, many women may shun medical care, because of fears about discrimination; loss of jobs, housing, insurance, relationships, and children. Furthermore, testing alone will not mandate adequate follow-up care, treatment, and other services. CDC recommends HIV counseling and voluntary testing, because this strategy has proven to be effective in getting women tested and treated in several communities nationwide, including Los Angeles, Atlanta, and Baltimore. At one inner-city hospital in Atlanta, for example, 96 percent of women chose to be tested after receiving HIV counseling and being offered a voluntary test as part of prenatal care. Compliance with routine counseling by physicians and acceptance of HIV testing by pregnant women is likely to greatly increase during the next year as a result of guidelines from PHS and professional organizations, which recommend it as a standard of practice.

It is important to remember that while HIV testing during pregnancy is a crucial step, it is not by itself the intervention. This important intervention will likely be most successful when it begins with an informed patient and a trusted provider. Voluntary testing accomplishes this; mandatory testing does not, and may actually reduce the chance a woman and her baby will receive needed therapies if they are alienated from the health care system.

I'd like to take just a few moments to discuss HIV testing of infants and what it can and cannot tell us. In most cases, mother-to-infant, or perinatal, transmission occurs during pregnancy or childbirth, although it is not possible to predict when transmission will occur for individual women and their children. Rarely, HIV has been transmitted through breast feeding.

However, not every infant born to an infected woman will be infected and subsequently develop AIDS. Studies have shown that a baby born to an infected woman has a 20 to 30 percent chance of being infected with HIV. Most infants born to infected mothers are NOT infected.

While only a fraction of babies are infected, all babies born to infected mothers will have a positive HIV antibody test at birth, which reflects the presence of the mother's antibodies.

All infected mothers pass these antibodies to their baby, but not all pass the virus. Thus, a positive HIV-antibody test in a newborn means that: (1) the mother has HIV infection, and (2) the newborn has been exposed to HIV and has a 20 to 30 percent chance of being infected.

In 1993 nearly 7,000 HIV-infected women (or about 1 in every 625 women giving birth) gave birth in the United States. Therefore, we estimate that 1,300 to 2,000 HIV-infected infants were born in the United States in 1993.

We know this, in large part, because of CDC's HIV surveillance activities, which I mentioned earlier, particularly the HIV Survey of Childbearing Women. CDC's HIV Survey of Childbearing Women was started in 1988 because it was clear that reporting AIDS cases alone, which reflects infections that occurred years earlier, would not provide a complete picture of the extent of the epidemic, including the epidemic among women. The goal of the survey has been to track HIV infection in women to provide information for planning health care resources, and to better target and evaluate services and care to two groups increasingly affected by HIV--women and children.

Forty-five states, as well as the District of Columbia, Puerto Rico, and the Virgin Islands, have participated in the survey. Funding with grants provided to the states by CDC has

provided "blinded" testing of 25 to 100 percent of specimens from newborns in a given state. Many states also provide support to supplement CDC's funding.

This survey has provided an important resource at the federal, state and community levels to develop and prioritize prevention programs, identify trends of HIV infection among women and children, and to project the need for, and costs of, health care services to care for HIV positive children and their affected parents. At the national level, the Public Health Service and professional groups have used survey data to assist in developing guidelines and recommendations, including the recommendations for HIV counseling and voluntary testing for pregnant women and their infants, and guidelines for PCP prophylaxis in children which I discussed earlier.

Today, with the recent advances in our ability to decrease perinatal transmission and slow the course of the HIV epidemic, and knowledge of the importance of early PCP prophylactic therapy for children with HIV infection, the CDC is re-evaluating how best to combine prevention and surveillance strategies to meet these important challenges. Implementation of the proposed CDC guidelines for counseling and voluntary testing of women and their infants must be a high priority as lives may be saved and suffering averted. Dr. Philip Lee, Assistant Secretary for Health will ask all States to immediately suspend the current

survey. We will convene a panel of outside experts to examine strategies to promote, implement, and evaluate in all States the CDC guidelines for counseling and testing of pregnant women and their infants and encourage the use of zidovudine to reduce the risk of perinatal transmission of HIV. Consultation with State public health officials, private providers, medical and ethical experts, providers caring for women and children with HIV disease, and communities affected by HIV will be most helpful to ensuring widespread acceptance and implementation of these guidelines. CDC is confident that its dual missions of prevention and monitoring the trends of the HIV epidemic can be fulfilled through a thoughtful public health strategy to implement the guidelines and evaluate their effectiveness.

In closing, I would like to say that we must keep our eye on our common goal of preventing HIV infection in women and children. We must also evaluate how effective our efforts are, including effective monitoring of HIV infection in women and children.

Mr. Chairman, thank you for this opportunity to discuss CDC's prevention activities and to share some of our thoughts on this important and complex issue. This concludes my testimony. I will be happy to answer any questions that you or other subcommittee members may have. Thank you.

Statement of
The Honorable Nancy Pelosi
On Preventing Perinatal HIV Transmission
May 11, 1995

Mr. Chairman, thank you for holding this hearing today on HIV testing for pregnant women and infants. I appreciate the opportunity to present my views. Your Committee has a great responsibility in assessing the complex issues surrounding this public policy debate.

I want to acknowledge and thank our colleague Gary Ackerman of New York for bringing much needed attention to this critical issue. In my view, we have many points of agreement. All sides of this debate agree that women and children are being diagnosed too late in the disease.

We also agree that babies have important rights and that government has a responsibility to protect vulnerable infants. That is why we have public policies addressing such issues as child abuse reporting where the need to protect children outweighs privacy rights of parents.

And finally, while care and treatment issues are of extreme importance, I think that we can agree that the best outcome for these babies is to prevent their becoming infected in the first place. Then, the question for this committee appears to be -- how do we best prevent the baby from becoming infected? The two initiatives proposed by CDC deserve your careful consideration.

The first is to establish practice guidelines for the counseling and voluntary testing of all pregnant women. A study of women at an inner-city hospital in Atlanta, found that 96% of women given prenatal HIV counseling voluntarily agreed to HIV testing. This suggests that cooperation with the practice guidelines will be high. However, some women are always going to be hard to reach.

Therefore, a second recommendation is to target pregnant women through community-level HIV prevention plans. As you may know, over the last year the CDC has initiated HIV prevention community planning all across the United States. The process involves local health departments working in partnership with representatives of groups most at risk of HIV infection to conduct comprehensive local HIV prevention plans.

In order to construct these local plans, CDC and local health departments provide the planning groups with the best available data on where new infections are occurring. The quality of the local plans is dependent on the quality of the data presented. Thus, health departments point to the importance of the HIV Survey in Childbearing Women.

It is important to differentiate between population-based survey research and medical testing which is used to make a diagnosis of HIV infection. As CDC will explain, there are many practical reasons why simply "unbinding" this study would not address the important goals that we all share of wanting HIV-infected babies to receive the highest possible quality of medical care. The Ackerman bill would prohibit this important survey and only permit individual diagnostic testing of newborns. Then the important question for this committee is -- what opportunities are lost if the survey is discontinued?

The Hawaii health department reports that this survey, where results are reported by zip code and hospital where the baby was delivered, recently gave them information on a new emerging pattern of infection among women in a particular community on one island. Then, the planning group for this island was able to target HIV prevention activities to these women at increased risk.

The Illinois health department reports that the survey pointed to four areas within the state with high prevalence of infected women. The state then directed counseling, testing and other support services to seven women's health clinics serving the majority of women at risk in these areas. The Florida health department reports that the survey has been extremely useful and is the only unbiased, population-based data available in Florida for making decisions on targeting prevention program for women and children.

For some Members of this committee, mandatory testing may seem a reasonable option. Whether blood is drawn from the pregnant mother or the newborn, the results will be the same. Because mandatory approaches disrupt the trust necessary to make informed medical decisions -- and therefore may lead to an increase in the number of infected infants -- I urge you to reject this option.

Others on the Committee are likely to believe that unblinding the newborn survey is a reasonable option. I agree with the public health officers -- this option is flawed because taking critical tools away from prevention planning is also likely to increase the number of infected infants. No matter how politically attractive, I urge you to reject this option.

I too believe we need to do something. So I urge you to find ways to legislatively encourage states to adopt the CDC guidelines. This approach will promote a trusting relationship between women and their health care providers -- and, most importantly, help prevent infants from becoming infected.

Again, I thank the Chairman and the Committee for the opportunity to present my views. I look forward to working with you to prevent HIV infection in women and newborns.

STATEMENT BY

JAMES BALSLEY, M.D.

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NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
NATIONAL INSTITUTES OF HEALTH

BEFORE THE

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

THE COMMITTEE ON COMMERCE

U.S. HOUSE OF REPRESENTATIVES

MAY 11, 1995

Mr. chairman, Members of the Subcommittee, I am pleased to appear before you to provide information regarding pediatric HIV infection. I am Chief of the Pediatric Medicine Branch of the National Institute of Allergy and Infectious Diseases. Specifically, I will provide a brief overview of Pediatric HIV and AIDS followed by a discussion of the prevention of perinatal transmission of HIV and in particular, the regimen used in one of our trials, ACTG 076. Finally, I will discuss some aspects of treating HIV-infected children that require early knowledge that the child is at risk.

Pediatric HIV Infection

The first reports of acquired immunodeficiency syndrome in children occurred in 1982. Risk factors for infection included transfusion with contaminated blood, treatment of hemophilia or other coagulation disorders with contaminated blood products, and transmission of HIV-1 virus from mother to infant *in utero* (before delivery) or at delivery. Currently the vast majority of new pediatric HIV cases are due to maternal-infant transmission. There are about 7000 deliveries per year in the U.S. by HIV-infected pregnant women, and about 2000 of these infants are infected with HIV.

Pediatric HIV is a devastating disease. Approximately 20 percent of these children become symptomatic early and will die before four years of age. The remainder have a median survival of about five years. There is no curative therapy for this disease. However, there are now available means to reduce the risk of acquiring pediatric HIV infection. In order for these interventions to be applied effectively, however, pregnant women should be aware of their HIV status, and must understand their disease and the treatment options available to them early in their pregnancy. Furthermore, specific treatment for the infant can prevent and treat complications of the disease and improve the duration of survival and the quality of life for those affected.

Prevention of Perinatal Transmission

Since nearly all new cases of HIV infection in children result from transmission from mother to infant, identifying ways to prevent such transmission is of high priority for NIH. Clearly, the most effective way to prevent perinatal transmission is to prevent maternal HIV infection. In the absence of accomplishing this, we must understand the biological features of maternal-fetal transmission so we can plan studies appropriately. Important features include the timing of transmission (gestation, delivery, post-delivery), the probability of transmission, risk factors which are predictive of transmission and the mechanism of transmission.

The estimated risk of HIV transmission from mother to child has varied from study to study. In the United States, however, there is a growing agreement that in the absence of intervention the overall risk is approximately 20 to 30 percent. This is comparable to the risk of maternal-infant transmission in much of the world, although in Africa it is somewhat higher, and in one large European study the risk was reported as low as 14 percent.

Mother to-child transmission of HIV can occur via breast feeding. A recent analysis involving data from four studies was conducted by scientists at the Institute of Child Health in London. They demonstrated that the additional risk of transmission through breast-feeding, over and above transmission *in utero* or during delivery, is approximately 14 percent. Thus, there is a significant increase in the risk of transmission when an HIV-infected mother breast feeds her infant. As a result, it is standard medical practice in the United States and other developed countries for HIV-infected women not to breast feed. Very few women in the US who know that they are HIV-infected breast feed their infants. So, except for those women who do not know that they are infected, breast feeding is not a major contributor to HIV transmission in the U.S.

Transmission of HIV can also occur *in utero* or during the labor and delivery process. It is not precisely known the extent to which transmission occurs *in utero* and at delivery. There is a growing body of evidence that 50 to 80 percent of transmissions occur during or very near the birth process, and that the remainder occur *in utero*. The specific timing of *in utero* transmission, however, is not known. The specific timing of transmission is important, since an intervention is less likely to be effective if it is applied significantly after the fetus or infant is exposed to the virus.

The risk of transmission is affected by a number of parameters related to the stage of maternal disease and the delivery process. Increased circulating maternal virus, as measured by culture of infectious virus or by polymerase chain reaction (PCR) methods (sensitive tests for viral genetic material), is associated with an increased risk of transmission. Similarly a decrease in CD4+ lymphocyte cells, the immune cells that are destroyed by HIV, is predictive of an increased risk of transmission. Increased duration of the rupture of membranes has also been reported to be associated with an increased risk of transmission.

Some scientists believe that cesarean section may be associated with a slightly reduced risk of transmission, but it is not known if such an intervention would be effective and it potentially increases morbidity for the mother. An ongoing clinical trial in Europe is designed to address this question. A recent study in Malawi also showed an association between severe vitamin A deficiency in HIV-infected pregnant women and an increased risk of transmission of HIV to their infants. Since vitamin supplementation is a part of prenatal care in the U.S., the relevance of this finding in the U.S. is not clear. It has been shown that in twin deliveries in which one twin acquires HIV from the mother and the other does not, there is a far greater chance of infection for the first born twin. This suggests that exposure to virus in the birth canal might be an important factor. A clinical trial, underway in Africa, is evaluating cleansing of the birth canal prior to delivery and the infant immediately after birth.

Interventions which have been or are being studied in the U.S. include the use of antiretroviral drugs, such as zidovudine (AZT), during pregnancy, delivery, and the first few weeks of life, which I will elaborate upon in just a few moments, and active and passive immunotherapy, alone or in conjunction with antiretroviral drugs. Antiretroviral drugs may act either by reducing the maternal viral load (level of virus), resulting in a lower exposure of infectious material to the infant and/or by reducing the susceptibility of the fetus or infant to infection by a given exposure. Active and passive immunotherapy might either reduce the maternal viral load or boost the protective immunity of the fetus or child.

ACTG 076

The Pediatric AIDS Clinical Trials Group (ACTG), with funding from the NIH, has carried out a clinical trial designed to evaluate whether a regimen of zidovudine (AZT) administered to a healthy HIV+ pregnant woman during pregnancy and delivery, and to her infant for six weeks after birth, could reduce the risk of transmission of HIV from mother to infant; this trial is known as ACTG 076. The results were published in the New England Journal of Medicine in November, 1994. Based on these findings, recommendations for the treatment of HIV-infected pregnant women were developed by a Public Health Service Task Force.

As background, in the late 1980s there was a growing body of evidence that zidovudine (AZT) could provide some protection against infection in animals exposed to viruses related to HIV-1. NIH-funded investigators in the ACTG developed ACTG 076 to determine whether a regimen of zidovudine (AZT) administered to pregnant women beginning and during pregnancy, during labor and to the infant during the first six weeks of life could reduce the risk of transmission of HIV from mother to infant.

Participants were HIV-infected pregnant women at 14-34 weeks gestation who had not received antiretroviral therapy during their current pregnancy. They had no clinical indications for antepartum antiretroviral therapy, and had CD4+ T-lymphocyte counts > 200/uL at the time of entry into the study. Women were randomized to receive either the zidovudine regimen or a placebo. The study began in April 1991; as of December 20, 1993, there were

477 women enrolled and 421 infants born. An evaluation of the trial by an independent data and safety monitoring board (DSMB) was held on February 18, 1994 using data through December 20, 1993. There was a highly significant reduction in the risk of transmission when comparing the active treatment group (those receiving zidovudine) to the placebo group. The risk of transmission in the treatment group was 8.3 percent compared to 25.5 percent in the placebo group. This corresponds to a 67.5 percent reduction in the risk of transmission. There was minimal toxicity in both the women and infants. The only demonstrable effect was a mild anemia in infants receiving zidovudine, which subsided after six weeks of age. The DSMB recommended a number of actions including that new mothers not be enrolled into the study.

These dramatic findings led to the release of an NIH Clinical Alert to inform physicians across the country of the results. A Public Health Service Task Force was subsequently formed in light of these results to develop treatment recommendations for the use of the ACTG 076 regimen by HIV-infected pregnant women and to review HIV screening guidelines for pregnant women. The PHS Task Force treatment recommendations were developed by a panel of experts and published in the Centers for Disease Control and Prevention (CDC) Morbidity and Mortality Weekly Report (MMWR) in August, 1994. The Food and Drug Administration approved the use of AZT for the prevention of mother to infant transmission of HIV and the results of the trial were published in the New England Journal of Medicine on November 3, 1994. At the time of publication, updated results from the study were available (since children from the trial were still being born). The updated estimates of the transmission rates were 7.9 percent for the zidovudine group and 27.7 percent for the placebo group.

Further analyses of this trial by NIH-supported scientists are ongoing and will be submitted for publication later this year. In particular, there will be an analysis of the relationship between maternal viral load, transmission, and the action of the drug AZT, as well as an assessment of maternal and obstetrical risk factors for transmission.

A major concern has been the potential for delayed effects on children exposed to the ACTG 076 regimen who are not infected with HIV. The Pediatric ACTG is conducting a follow-up protocol, ACTG 219, to detect these effects. Infants born on ACTG 076 and other perinatal transmission studies are eligible to enroll. They will be followed up to 21 years of age for physical and neurological growth and development, as well as for signs of organ specific toxicity and malignancy. To date, there has been no evidence that the regimen has a deleterious effect on these infants.

Similarly, there is concern about the long-term effects of the ACTG 076 regimen on the women who participated in the trial. Although the duration of zidovudine use was short, there is some concern that there could be an increased risk of the women developing AZT-resistant virus during the study, which would impact their use of this drug in the future. This and other potential long-term effects of the regimen are being evaluated in ACTG clinical trials, such as ACTG 288.

Since the only significant cause of HIV infection in young infants in the U.S. is transmission of virus from mother to infant, the potential impact of widespread use of the ACTG 076 regimen to reduce transmission is great. A reduction by 1/2 to 2/3 in the number of new cases of HIV in children would be a significant reduction in human suffering and in the burden of pediatric HIV on the health care system.

The regimen studied in ACTG 076 was designed to have the greatest chance of being effective, given the knowledge available at the time it was developed. Questions which remain today include: Can the intervention be started later in pregnancy? Is it necessary to use intravenous AZT in labor, or can oral dosing be used? Can the treatment of the infant after birth be shortened or eliminated without losing efficacy? Further research sponsored by the NIH, CDC, and other organizations around the world is in progress with the goals of improving and simplifying the regimen.

Treatment of Pediatric HIV

Treatment of HIV in children consists of therapy directed at the virus itself using antiretroviral drugs such as AZT, ddI, d4T, ddC, and prophylactic therapy designed to prevent opportunistic infections which can be fatal early in life. It is important to recognize that some aspects of treatment necessitate identification of children at risk of HIV within the first few weeks of life.

Young infants with HIV infection are susceptible to an opportunistic infection known as *Pneumocystis carinii* pneumonia (PCP). This infection causes a high mortality rate in children with HIV and is frequently the first recognized clinical sign of HIV infection in these patients. There is a highly effective prophylaxis regimen that can prevent PCP pneumonia in HIV-infected children. The use of the antibiotic trimethoprim/sulfa (SMX) beginning at 4-6 weeks of life can greatly reduce the risk of early death from PCP. Treatment is recommended by the CDC for children born to HIV-infected women and is continued until the child is proven to be uninfected. Use of this intervention requires knowledge that the child is at risk for perinatal transmission of HIV.

Antiretroviral drugs are currently initiated when a child becomes symptomatic or shows laboratory evidence of damage to the immune system. Current medical practice has been to initiate treatment with AZT as a single agent. The use of combinations of drugs, and other drugs, is currently being studied within the Pediatric ACTG.

Evidence indicates that significant damage to the immune system occurs within the first few weeks of infection. Thus, there is a possibility that early intervention (within the first few days or weeks of life) with effective antiviral agents might greatly alter the course of the disease. The Pediatric ACTG is working towards developing such an approach.

The long-term prognosis for children with HIV infection is grave. Continued progress in therapeutics can be expected to improve quality of life and survival time. Early identification of children at risk for HIV infection can also enhance their chances for survival since PCP prophylaxis can be initiated by 6 weeks of life, according to recently issued CDC guidelines. To date, prevention of infection, through regimens such as the one used in ACTG 076, is the most optimal medical intervention.

Conclusion

In summary, there are interventions that can reduce the risk of HIV transmission from mother to infant when the mother's HIV status is known during pregnancy. The NIH remains committed to pursuing additional research to improve upon and refine these and other techniques for the prevention of perinatal transmission and the treatment of HIV-infected children.

Thank you again for the opportunity to describe NIH's research activities in pediatric HIV disease and perinatal transmission. I appreciate your attention to these very important areas of research. I would be happy to answer any questions.

STATEMENT

of the

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

on

ISSUES IN HIV TESTING OF WOMEN AND INFANTS

Presented By

Michael T. Mennuti, MD, FACOG

before the

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

COMMITTEE ON COMMERCE

U.S. HOUSE OF REPRESENTATIVES

May 11, 1995

Mr. Chairman and Members of the Subcommittee, I am Michael T. Mennuti, MD, a professor of Obstetrics and Gynecology at the University of Pennsylvania, a practicing obstetrician-gynecologist, and Chair of the American College of Obstetricians and Gynecologists' (ACOG) Committee on Obstetric Practice. On behalf of ACOG, an organization representing more than 35,000 physicians dedicated to improving women's health care, I appreciate the opportunity to testify today on the testing of women and infants for the Human Immunodeficiency Virus (HIV). This issue poses complex medical and ethical concerns for obstetrician-gynecologists and their patients, and I am pleased to assist the Subcommittee as it explores these complicated issues.

As primary care physicians for women, obstetrician-gynecologists have experience dealing with the devastating impact HIV and AIDS have on women and, for pregnant women, on their newborns. These impacts are not limited to medical consequences, but also those relating to finances and psycho-social well being. Unfortunately, I am increasingly seeing patients with HIV infection, as women represent the fastest growing population of new HIV infections in the United States. Women with HIV infection may pass the infection to their newborns. Usually this transmission occurs during pregnancy or more often during labor and delivery. It is estimated that approximately 7,000 children are born to HIV-infected mothers each year.

ACOG has made recommendations to its Fellows regarding education of their patients to prevent HIV infections from occurring, as well as treatment of HIV infection. With regard to counseling

for HIV, ACOG recommends that obstetrician-gynecologists counsel all patients about the risks of HIV infection. Public health messages about sexual practices that reduce the risk of HIV infection must be reinforced by health care providers as a routine part of primary health care. For example, when contraception is discussed, women should be informed about HIV infection and transmission and how to lower the risk of sexual transmission. ACOG feels strongly that ob-gyns and other primary care physicians have an obligation to help women understand this devastating disease, how to avoid it, and how to prevent its transmission to other individuals. Clearly, the most effective way to prevent HIV infections in infants is to prevent HIV infection in women.

In addition, ACOG recommends that voluntary and confidential HIV antibody testing should be offered to all women. Testing should only be offered in conjunction with appropriate counseling and informed consent. Further, for those women at risk for acquiring the disease, ACOG recommends that the ob-gyns especially encourage testing. To determine which women are at risk, a comprehensive patient history-taking must be done and the Centers for Disease Control and Prevention's definition of risks for HIV infection should be used. Women who are infected with HIV need to be counseled to decrease the risk of infection to their partners and women who test negative need to be counseled in order to remain uninfected.

Some have argued that counseling and testing recommendations should be modified due to the recent findings of the NIH-sponsored AIDS Clinical Trial Group (ACTG) study on the efficacy, safety, and tolerance of zidovudine (ZDV) for the prevention of vertical transmission of HIV.

Before addressing the testing issue, what we have learned from this study should be reviewed. Referred to as ACTG 076, the randomized, placebo controlled trial produced data which showed significant evidence of treatment efficacy. Specifically, the trial demonstrated a 67.5 %-reduction in transmission risk with the administration of ZDV in study participants. The estimated rate of vertical transmission in the control group was 25.5 %, compared with 8.3 % in the treated group.

While this study gives us important information, we must be cautious in attaching too much significance to this study. First, relying on only one study always poses the risk of misinformation. In addition, the study leaves many questions unanswered. For example, the study population was too small and the duration of the follow-up too short to detect adverse effects of the treatment on the women or their infants. It is not known whether treatment with ZDV during pregnancy will affect the development of resistance to ZDV should the drug be required subsequently for the woman's health. ZDV can have severe side-effects in some patients. The ACTG study does not define the lowest possible effective dose of ZDV for the prevention of vertical transmission or the relative contribution of each component of the treatment as in the study ZDV was administered to the mother prenatally, during labor and delivery, and to the neonate. Finally, because this study involved only patients who met well-defined criteria, the benefit of prophylactic ZDV in patients who do not meet the study criteria remains uncertain.

Although the 076 findings are encouraging, we must remember that ZDV was not successful in

preventing all vertical transmissions. Accordingly, women with HIV infection still face difficult treatment and reproductive decisions.

Any discussion of HIV testing in pregnant women must begin with the understanding that a woman's knowledge of her HIV status is of vital importance for the sake of her own health. This fact was true prior to the 076 study and remains equally true today. Only after HIV-infection has been identified can women and their doctors begin necessary treatment and appropriate care. Unfortunately for many with HIV, access to care is in many cases minimal or nonexistent. Ensuring that such care is available must be a top priority for us all.

Identifying infection is the first step towards seeking such care for women. The issue then becomes how women can best learn their HIV status. Some have suggested that government-mandated testing is the answer. ACOG disagrees. The responsibility to counsel and offer voluntary testing for HIV to patients falls within the current physician-patient relationship and we believe it must remain here.

Coercion, such as mandatory HIV testing for pregnant women, should not be imposed by government, as it is not desired by women, nor is it desired by their physicians. There are numerous examples which demonstrate the failures of mandatory HIV testing policies. When HIV testing is mandatory in an office or clinic setting, individuals simply stop going to that physician or clinic. This was highlighted most recently in New York, where women with HIV stated that they would not seek care from physicians who required HIV testing at prenatal care

visits. Unfortunately, the stigma attached to HIV in certain communities still precludes many women from seeking out their HIV status. Government-enforced HIV testing only heightens this stigma, particularly in communities of color where mistrust of the public health system has been longstanding. These barriers can only be overcome by objective, informed, and non-coercive counseling from a knowledgeable and respected source, such as a physician, coupled with confidential and voluntary HIV testing.

Federal policies requiring physicians to perform HIV tests on their patients would be an unwelcome intrusion on a physician's ability to practice medicine in keeping with current standards of care and a patient's ability to obtain their own physician's best judgment about health care. ACOG's current recommendations that ob-gyns educate patients about the risks of HIV and offer confidential, voluntary HIV testing to all patients has proven successful for many ob-gyns who have experienced high rates of patients consenting to HIV tests during pregnancy.

In conclusion, it is important to emphasize that any policy with regards to HIV testing must recognize the fact that pregnant women, provided with accurate information, must be allowed to make decisions that they determine to be best for themselves and their infants. Experience shows that when faced with a decision that effects the health of their newborn, women who have been presented accurate information generally make the decision that is in the best interest of the health of their child.

It is a physician's responsibility to ensure that accurate information is provided and to provide

his or her best medical opinions with regards to HIV testing and treatment options. ACOG firmly believes that federal mandatory HIV testing policies will deter physicians' ability to provide these options to their patients and recommends that such policies be rejected by the Congress at this time.

I thank the Subcommittee for the opportunity to testify today on behalf of ACOG. I would be happy to answer any questions Members may have.

Opening Statement of Congressman Henry A. Waxman
At Hearings on HIV Testing of Pregnant Women and Newborns

Today's hearing is on one aspect of an important topic: How best to prevent HIV infection of newborns and how best to provide health care services to those newborns who are infected. More narrowly, this hearing focuses solely on HIV testing as a means to accomplish this end.

Everyone agrees on the goal: Prevention of HIV infection in children.

The good news of the NIH findings on AZT during pregnancy is that there is hope that infection can be prevented with drug treatment and this takes the Nation one step closer to preventing pediatric AIDS. The CDC guidelines have given the steps to making this hope a reality. Pregnant women should be counseled and tested, and infected women should be encouraged to take AZT to reduce the risk of fetal transmission. Such counseling, testing, and drug therapy should become the standard of care for all pregnant women.

But people do disagree about the most effective way to accomplish this goal.

Some people argue that mandatory testing is the only way to get women tested. The data show just the opposite.

In site after site--in New York, Atlanta, and Miami--about 95% of pregnant women agreed to be tested voluntarily after they were counseled. Some of these studies were even conducted before there was a preventive measure, and these numbers will surely rise now that we can offer mothers hope for their children.

And in place after place--from Illinois' mandatory AIDS testing for marriage licenses to other experiments in mandatory drug testing in drug abuse treatment programs--people stay away from places with mandatory testing, where tests will be conducted against their will. Health care professionals who work with poor women at high risk report that we can expect the same in this instance: these women are very afraid that HIV tests will be used against them; they especially fear the loss of custody of their children.

I am not doubting the sincerity of those who argue for mandatory testing. They believe that this will work to slow pediatric AIDS, the goal that we all share.

But I am afraid such policies will backfire: Many women--perhaps more than the small number who decline voluntary HIV testing--will be frightened from prenatal care, and the result will be a loss for AIDS prevention and maternal and child health in general. Ironically, the result may be that more children die from AIDS, rather than fewer. We should not take this risk when we have never given voluntary testing a chance.

We should also immediately implement all other actions to encourage prevention of pediatric AIDS. We should educate the public about the value of testing, and we should educate health professionals about the new standard of care for pregnant women.

And we also must remember that this testing is useless unless we also provide the means to prevent the infection. We all agree that this is our goal; I hope we can all agree also that we will take the steps to make it a reality. It is not sufficient simply to provide testing: We must also provide the AZT, pneumonia prevention, TB prevention, and other primary care that these people need. Medicaid is the source of health care for most of them. We must ensure that Medicaid provides these services without restriction and to everyone who needs them.

I am asking all my colleagues who share my goal of preventing pediatric AIDS to join with me in ensuring that every State Medicaid program, every ERISA plan, and every health insurance program provides full and unrestricted access to these vital services for pregnant women and newborns and to join with me to provide a safety net for those women and children with no coverage at all.

With such action, we will do more to lower pediatric infection rates than any mandatory test ever will. If we do not do so, we will be making the promise of prenatal testing into a cruel hoax.

Finally, I want to say that I hope we can place this topic within the larger context of prevention of HIV infection. Ultimately, the best way to prevent pediatric HIV is to prevent adult HIV. If mothers and fathers are uninfected, fetal transmission of the disease is not an issue. To this point, however, the Nation's prevention efforts have been too little and, in many cases, too late. I hope we will be looking at these issues soon and that we will give comprehensive AIDS prevention the attention it deserves.

ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS

TESTIMONY ON HUMAN IMMUNODEFICIENCY VIRUS (HIV) TESTING

PRESENTED BY

**DAVID MULLIGAN
COMMISSIONER
MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH**

TO

**HOUSE COMMERCE COMMITTEE
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT**

MAY 11, 1995



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SUMMARY OF TESTIMONY

Reported cases of AIDS in children continue to increase. The Centers for Disease Control and Prevention (CDC) estimates about 1,000-2,000 HIV infected infants were born in the United States in 1993. The results of the AIDS Clinical Trial Group (ACTG) 076 indicate that zidovudine (AZT or ZDV) can reduce perinatal HIV transmission by as much as two-thirds. The results offer significant opportunity to prevent perinatal transmission of HIV. ASTHO applauds the efforts of the Public Health Service and CDC to disseminate the results of ACTG 076.

ASTHO believes the best way to prevent HIV infection in newborns is to prevent HIV infection in women. Recognizing that the epidemiology of the AIDS epidemic varies across states, ASTHO recommends that all women of childbearing age be provided with routine HIV education, counseling and voluntary testing, as appropriate for the HIV prevalence of the area. States should develop a plan to implement this recommendation, that considers the prevalence of HIV in their state population. ASTHO recognizes that implementation of the guidelines will require additional funding and technical assistance from the federal government to educate providers and the community, and to ensure that HIV infected women are provided with the appropriate treatment and care services.

The enhanced medical therapies that may prevent HIV transmission, prolong, and improve the quality of life should not compel Congress to abandon or change critical surveillance systems, but should be the basis to ensure that the population is provided with the access to appropriate preventative, medical and care services in an environment that considers individual autonomy. Additionally ASTHO recommends:

- Congress should support states in developing comprehensive strategies to implement the results of the ACTG 076 trial and to provide the medical and support services to women and children which are critical to preventing HIV infection.
- Any national policy should respect the CDC Community Planning Initiative, a process that allows communities to participate in the development of local HIV prevention strategies. National policies should be cost-effective, ensure state and local flexibility, and consider the varying HIV prevalence in states and locales.
- Congress should increase funds for existing public health programs which address HIV prevention and the needs of women and children, such as CDC's HIV prevention programs, the Ryan White CARE Act and the Maternal and Child Health Block Grant.
- Congress should reauthorize the Ryan White CARE Act, which provides critical medical and support services and medications to HIV-infected women and their children.

Good afternoon, my name is David Mulligan, Commissioner of the Massachusetts Department of Public Health. I am here today on behalf of the Association of State and Territorial Health Officials (ASTHO). ASTHO represents the public health departments in each of the 50 states, the District of Columbia and the U.S. territories. I thank you for the opportunity to present state health officials' perspectives on the important public health issue of HIV testing in women.

Background/Epidemiology

According to the Centers for Disease Control and Prevention (CDC), the Acquired Immune Deficiency Syndrome (AIDS) is currently the leading cause of death among persons ages 25-44 in the United States, and the fourth leading cause of death among women in the same age group.¹ In 1994, 18 percent of AIDS cases in persons age 13 or older occurred among women. Of key concern, the AIDS epidemic continues to affect racial and ethnic minorities disproportionately: currently three fourths of the AIDS cases in women occurred among blacks and Hispanics. In 1993, AIDS was the leading cause of death among black women aged 25-44, and the third leading cause of death among Hispanic women in the same age group.

An HIV infected woman has a one in four chance of transmitting the virus to her fetus or newborn during pregnancy, labor or delivery. Subsequently, the increase in the rate of AIDS in women has been reflected by a similar increase in children; more than 95% of AIDS cases in children from birth to 4 years old are caused by perinatal infection. Despite tireless public health efforts, more than 100,000 women of childbearing age in the U.S. are infected with HIV. Each year some 7,000 infants are born to these women, and of these infants, considering a 25 percent transmission rate, 1,000-2,000 become HIV infected. As of 1993, pediatric AIDS was

¹ *Morbidity and Mortality Weekly Report*, February 10, 1995, Vol. 44, No. 5.

the seventh leading cause of death among children 1-4 years old.

The prevalence of HIV infection in women and newborns varies tremendously across the nation, and is not limited to urban areas. Today more than 25 percent of women with AIDS are from smaller cities and rural areas of the United States². CDC reports that in 1994, the Northeast region accounted for the largest percentage of AIDS case reported among women, followed by the South, West, Midwest, and Puerto Rico and the U.S. territories. Currently, 34 states have reported fewer than 50 cumulative cases of pediatric AIDS.

Response to the AIDS Clinical Trial Group (ACTG) 076

Results of the AIDS Clinical Trial Group (ACTG) 076 released in February 1994 indicate that zidovudine (ZDV) administered to pregnant HIV-infected women may decrease the rate of perinatal HIV infection. This represents a significant medical breakthrough in the fight against perinatal transmission of HIV. ASTHO applauds the efforts of the Public Health Service (PHS), the National Institutes of Health and CDC to disseminate and respond to the results of the study.

In areas of both low and high prevalence of HIV/AIDS in women, state health departments have responded to the results of ACTG 076 by disseminating information about the benefits of ZDV therapy and the importance of HIV counseling and voluntary testing for pregnant women to providers and the communities they serve. State health departments have bolstered existing efforts to identify HIV-infected women and have developed new prevention programs that specifically address the care and treatment needs of HIV-infected women and their children.

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

Health departments have also convened committees of providers, HIV-infected women, and public health officials to develop treatment and HIV counseling and testing recommendations. State health departments are working with their Medicaid agencies to ensure that HIV counseling and testing and the full range of recommended services in the continuum of HIV/AIDS care are available to women and children, and have expanded their Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Title II drug reimbursement programs to ensure that HIV-infected women and their newborns can access appropriate medications. These efforts have largely been funded with state dollars and have not been supplemented with additional federal funds.

ASTHO members participated in the Public Health Service (PHS) interagency task force charged with developing the treatment guidelines that were published in the August 5, 1994 *Morbidity and Mortality Weekly Report*. ASTHO took further action to convene a task force to discuss the many policy, prevention and treatment issues related to the results. The task force is comprised of ASTHO members, a representative of the National Association of County and City Health Officials (NACCHO), and representatives of our affiliate organizations the Association of Maternal and Child Health Programs, (AMCHP), the Association of State and Territorial Public Health Laboratory Directors (ASTPHLD), the Council of State and Territorial Epidemiologists (CSTE), and the National Alliance of State and Territorial AIDS Directors (NASTAD). The task force developed a survey of state HIV counseling and testing policies as they relate to pregnant women, the results of which we believe are essential to crafting any national policy and that form the basis of the ASTHO recommendations related to pregnant women and newborns that I will share with you today.

Implications of ACTG 076 on Prevention of Perinatal Transmission of HIV

Since the beginning of the AIDS epidemic, diagnosis of HIV infection before or during pregnancy has been pivotal to preventing perinatal transmission. However, before the results of the ACTG 076 study were released, women were restricted in their options to prevent HIV transmission to their newborns. Options included avoiding or terminating pregnancy, and avoiding breastfeeding. The results of the ACTG 076 trial further emphasize the importance of prenatal care which allows women the opportunity to become aware of their serostatus so that they may avail themselves of the advances in HIV/AIDS treatment and prevention, such as ZDV therapy or *Pneumocystis carinii* Pneumonia (PCP) prophylaxis for the newborn.

HIV counseling and testing, as discussed in the CDC draft recommendations for pregnant women, allows both uninfected and infected women to assess their risk for HIV infection and initiate or reinforce HIV risk reduction behaviors. Counseling and voluntary testing provides HIV-infected women the opportunity for early diagnosis and treatment, allows them to make informed reproductive decisions, provides information on the methods for reducing the risk of perinatal transmission, and refers them to other medical and support services.

ASTHO believes the best way to prevent HIV infection in newborns is to prevent HIV infection in women. *Therefore, ASTHO recommends that all women of childbearing age be routinely provided HIV education, counseling and voluntary testing, as appropriate to the epidemic in their region. The recent ASTHO survey of state counseling and testing policies indicates that every state health agency in the United States ardently opposes mandatory HIV testing of pregnant women, and overwhelmingly supports voluntary HIV testing as the most effective strategy for preventing perinatal transmission of HIV.*

The necessity and importance of voluntary testing is artfully described in a statement by the American Academy of Pediatrics: "a relationship of respect and trust between women and the health care system is critically important to the identification of women who are HIV-infected and their subsequent care and treatment...the purpose of HIV testing is to engage a woman in continuing care for herself and her baby, not to label a woman as being infected. Compliance with medical care is likely to be greatest when the patient feels she has made an informed judgement regarding HIV testing for herself or her infant³."

The Public Health Service recommendations on the use of ZDV to reduce perinatal transmission of HIV advise that ZDV be administered five times daily, initiated during the 14th to 34th week of pregnancy and continued throughout the pregnancy, during labor, delivery and to the newborn for the first six weeks of life. Last week, CDC recommended that PCP prophylaxis be administered to infants within the first 4-6 weeks of life. Such treatment regimens for both the woman and her child require the cooperation of the woman, which is unlikely to occur if she has been forcibly tested. Furthermore, my public health colleagues vehemently believe that the fear of mandatory testing may have the deleterious effect of deterring women from seeking prenatal care, which is essential to our efforts to reduce infant mortality and morbidity.

The preliminary results of the ASTHO survey indicate that in 38 states HIV counseling and testing is not currently a standard of prenatal care. The 15 states that report HIV counseling and testing is a standard of prenatal care question the extent to which it is being adopted by private providers. *To this end, ASTHO has recommended that all states develop a plan appropriate to the epidemic in their population to implement the recommendation that all women of childbearing age be provided with routine HIV counseling, education, and voluntary testing.*

³ "Perinatal Human Immunodeficiency Virus Testing," *Pediatrics*, Vol.95 No.2, February 1995.

As states continue efforts to develop such plans, it is critical that we be provided with the tools to evaluate their efforts. Because the plans for implementing the results of the ACTG 076 trial will take into account the prevalence of HIV infection, we ask Congress to support seroprevalence studies that provide states with these important data.

The reason I was able to provide you with the epidemiological data on HIV infection in women is because of the HIV Survey in Childbearing Women. The survey is the most accurate and valuable source of data used by state health departments to determine the course and extent of the HIV epidemic in women, target scarce prevention resources, and plan medical and support services for HIV-infected women and their newborns. The survey in women is an epidemiological study conducted in 45 states, the District of Columbia, Puerto Rico, and the Virgin Islands. Many states (including the Commonwealth of Massachusetts) conduct the survey for every birth. Other states such as Illinois and California conduct the study only for a few months a year and extrapolate the results to all newborns. Samples for the study are obtained from leftover blood specimens collected for routine newborn metabolic screenings. All personal identifiers are removed before the samples are screened for HIV antibody testing.

The survey detects HIV antibodies which indicate infection in women and only **some** of their newborns. Since maternal HIV antibodies cross from pregnant women to their fetuses through the placenta, all children born to HIV positive women will test positive at birth. Only approximately 25 percent of these babies are actually infected. The child's immune system will shed maternal antibodies within the first 18-20 months of life and will begin to produce its own HIV antibodies **only** if the child is infected.

The key to the success of the survey is that blood from everyone is tested, and thus the results apply to the entire population. To the extent that consent is required for the survey, the results

are worthless. To the extent that testing is mandatory, we will jeopardize the entire newborn metabolic screening program, as women and their providers may not consent to any of the newborn screening tests. States may be forced to abandon doing any HIV testing in the newborn setting. The blinded nature of the study is essential to the methodology of this survey which is critical for monitoring the HIV epidemic in childbearing women.

H.R.1289, a bill introduced by Representatives Gary Ackerman and Ileana Ros-Lehtinen, destroys the usefulness of the survey and will not accomplish the goal of identifying HIV infected infants. Although the goal of this bill is laudable, "saving babies," ASTHO believes that the best method of accomplishing this goal is ensure that in regions where the HIV prevalence warrants, women of childbearing age are provided with routine HIV counseling, education and voluntary testing, and treatment services that reduce the risk of perinatal HIV transmission.

The enhanced medical therapies that may prevent HIV transmission, prolong, and improve the quality of life should not compel Congress to abandon or change critical surveillance systems, but should be the basis to ensure that the population is provided with the access to appropriate preventative, medical and care services in an environment that considers individual autonomy. Additionally ASTHO recommends:

- **Congress should support states in developing comprehensive strategies to implement the results of the ACTG 076 trial and to provide the medical and support services to women and children which are critical to preventing HIV infection.**
- **Any national policy should respect the CDC Community Planning Initiative, a process that allows communities to participate in the development of local HIV prevention strategies. National policies should be cost-effective, ensure state and**

local flexibility, and consider the varying HIV prevalence in states and locales.

- **Congress should increase funds for existing public health programs which address HIV prevention and the needs of women and children, such as CDC's HIV prevention programs, the Ryan White CARE Act and the Maternal and Child Health Block Grant.**

- **Congress should reauthorize the Ryan White CARE Act, which provides critical medical and support services and medications to HIV-infected women and their children.**

I commend the committee for addressing this important public health issue and thank you for the opportunity to share state health officials' perspectives.

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SUBCOMMITTEE ON HEALTH AND ENVIRONMENT

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TIME: 1:00 p.m. in Room 2322 Rayburn House Office Building
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TESTIMONY
OF THE
AMERICAN ACADEMY OF PEDIATRICS
BEFORE THE
HEALTH SUBCOMMITTEE
OF THE
COMMERCE COMMITTEE
U. S. HOUSE OF REPRESENTATIVES
ON
PEDIATRIC HIV TESTING

Presented by:

Louis Z. Cooper, MD

May 11, 1995

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

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

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

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

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

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

BACKGROUND

Human immunodeficiency virus infection continues to spread among women of childbearing age in the United States, and is occurring in rural as well as urban areas. In 1993, 12.6 percent of new AIDS cases were diagnosed in women -- up from 6 percent in 1982. (1,2) With the increasing heterosexual spread of HIV, previously defined risk behaviors for HIV infection incompletely identify women found to be infected. The predominant risk behavior for HIV infection in many women is unprotected sexual intercourse. Perinatal HIV infection has mirrored the increases in HIV infection in women. More than 95 percent of AIDS cases

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

The persisting occurrence of PCP in young infants despite the availability of effective prophylactic regimens indicates that the identification and treatment of HIV infection in infants at an early age remains inadequate. (3)

AAP POLICY ON PERINATAL IMMUNODEFICIENCY VIRUS (HIV) TESTING

On the basis of recent advances in the therapy to reduce the rate of perinatal HIV transmission and the continued occurrence of life-threatening illness in young infants with unrecognized HIV infection, the AAP recommends: **"Documented, routine HIV education and routine testing with consent for all pregnant women in the United States."** A copy of the full AAP policy statement is attached.

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

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

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

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

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

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

Routine HIV Education: Routine education about HIV infection and testing needs to be a part of a comprehensive program of health care for women, particularly for women of child-bearing age. Detection of HIV infection may be associated with anxiety and depression. Other risks include potential social stigmatization and discrimination. Also, because illicit intravenous drug use is associated with HIV infection and may be used as a basis to remove an infant from the mother's care, women who use illicit drugs may fear HIV testing.

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

Women need to be given sufficient information in a clear and understandable manner to appreciate the benefits and risks of the proposed HIV test and the consequences of accepting or rejecting testing for herself and her infant. This process is best performed within the context of a professional relationship between the woman and her health care provider. It is possible if the benefits of HIV testing are not made known to pregnant women, fear of the potential negative consequence may deter some women from seeking prenatal care. However, in several settings in which HIV counseling and voluntary testing have been routinely offered to all prenatal patients, no measurable decrease in women seeking prenatal care has been observed.

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

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

- 1) Individualized counseling followed by a signature that affirms consent to testing;
- 2) provision of education followed by a signature that either explicitly consents to or explicitly refuses testing; or
- 3) education followed by a signature only to explicitly refuse the test.

Each of these methods is an ethically acceptable way to respect the individual's decision whether or not to be tested. The Academy supports utilization of consent procedures that facilitate rapid incorporation of HIV education and testing into the routine medical care

setting. Whichever method of obtaining consent is chosen, it is critically important that appropriate education regarding HIV infection is provided to the individual before a decision regarding testing.

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

TESTING NEWBORNS

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

For newborns whose mother's HIV serostatus was not determined during the recent pregnancy or the postpartum period, the infant's health care provider should educate the mother concerning the potential benefits of HIV testing for her infant and the possible risks and benefits to herself of knowing the child's serostatus and recommend HIV testing for the newborn.

The health care provider for the infant needs to be informed of maternal HIV serostatus so that appropriate care and testing of the infant can be accomplished. Similarly, if the infant is found to be seropositive when maternal serostatus is unknown, the health care provider for the child should ensure that information about the serostatus and its significance be forwarded to the mother and, with her consent, to her health care provider. The mother should receive appropriate referral to adult HIV-related services.

Because infant testing provides information important to the well-being of the infant and also information regarding the infection status of the mother, the health care provider is obligated to educate the mother about HIV infection and to obtain consent using one of the methods described above when HIV testing of the infant is contemplated. In the absence of parental availability for consent to test the newborn for HIV antibody, procedures need to be established to facilitate the rapid evaluation and testing for the infant.

CONCLUSION:

As noted, there are now clear medical benefits for pregnant women to know their HIV serostatus. In addition to the importance HIV testing has for early diagnosis and treatment of women, the availability of treatment capable of significantly reducing perinatal transmission of HIV provides compelling rationale and motivation for all pregnant women to know their HIV serostatus during early pregnancy.

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

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

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

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

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

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

populations are being met.

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

1. Centers for Disease Control. Update: acquired immunodeficiency syndrome -- United States, 1992. *MMWR*. 1993;42:547-551,557
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3. Hsu HW, Moye J Jr, Kunches L, et al. Perinatally acquired human immunodeficiency virus infection; extent of clinical recognition in a population-based cohort. Massachusetts Pediatric HIV Surveillance Working Group. *Pediatr Infect Dis J*. 1992;11:941-945
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5. Lindsay MK, et al. Routine antepartum human immunodeficiency virus infection screening in an inner-city population; *Obstetrics and Gynecology*. 1989;74:289-294

Attachment

Perinatal Human Immunodeficiency Virus Testing

Provisional Committee on Pediatric AIDS

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

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

CHANGING EPIDEMIOLOGY OF HIV INFECTION IN WOMEN OF CHILDBEARING AGE

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

In addition to the increasing incidence of AIDS in women, cases are no longer confined to urban areas of the United States; currently, more than 25% of women with AIDS are from smaller cities and rural areas of the United States.³ Furthermore, behavioral risk factors for HIV infection in women are shifting. Since 1992, heterosexual contact has exceeded

intravenous drug use as the primary exposure category in women with AIDS. A significant proportion of HIV-infected women are not aware of their own or partner's risk for HIV infection. Evaluation of national data from publicly funded HIV counseling and testing services from 1989 to 1990 indicates that 35% of women found to be HIV-infected do not report risk factors that have been commonly associated with HIV acquisition, such as intravenous drug use or having sex with a partner at known high risk for HIV infection; 44% of black seropositive women did not report these behaviors.⁴ Unprotected sexual intercourse may be the only high risk factor for HIV acquisition for these women.

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

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

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

USE OF ZIDOVUDINE TO REDUCE PERINATAL HIV TRANSMISSION

The risk of perinatal HIV transmission can be reduced through the administration of zidovudine to HIV-infected pregnant women and their infants. Interim results have recently been reported from a randomized, double-blind, placebo-controlled clinical trial, AIDS Clinical Trial Group (ACTG) Protocol 076, that evaluated the use of zidovudine administered during pregnancy, labor, and to the newborn to reduce perinatal HIV transmission.¹ This trial enrolled HIV-infected pregnant women with early stage HIV disease (CD4 count of 200 cells/mm³ or above at the time of entry into the study, who had

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

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

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

DIAGNOSIS AND MANAGEMENT OF PEDIATRIC HIV INFECTION

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

Because of the age distribution of infants with PCP, PCP prophylaxis should begin in the first months of life, which requires recognition of the

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

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

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

BENEFITS OF HIV TESTING IN THE PRENATAL AND NEWBORN PERIODS

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

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

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

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

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

RISKS OF HIV TESTING IN THE PRENATAL AND NEWBORN PERIODS

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

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

THE ISSUE OF CONSENT FOR HIV TESTING

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

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

Some states have legal requirements for counseling followed by written consent for HIV testing. Routinely used methods in medical practice to document consent or refusal for medical procedures other than HIV testing include: 1) individualized

counseling followed by a signature that affirms consent to testing; 2) provision of education followed by a signature that either explicitly consents to or explicitly refuses testing; or 3) education followed by a signature only to explicitly refuse the test. Each of these methods is an ethically acceptable way to respect the individual's decision whether or not to be tested. Each method, however, has different associated dimensions.

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

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

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

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

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

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

CONCLUSION

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

RECOMMENDATIONS

1. On the basis of recent advances in therapy to reduce the rate of perinatal HIV transmission and the continued occurrence of life-threatening illness in young infants with unrecognized HIV infection, the AAP recommends documented, routine HIV education, and routine testing with consent, for all pregnant women in the United States. Documented consent for maternal and/or newborn HIV testing may be obtained in a variety of ways, including by right of refusal (documented patient education, with testing to take place unless rejected in writing by the patient). The Academy supports utilization of consent procedures that facilitate rapid incorporation of HIV education and testing into the routine medical care setting.
2. Routine education about HIV infection and testing needs to be a part of a comprehensive program of health care for women, particularly for women of child-bearing age.
3. All testing programs for the detection of HIV infection should periodically evaluate the proportion of women who refuse HIV testing following HIV education. Those programs in which a proportionately low number of women receive HIV testing should examine the reasons for poor acceptance, with appropriate program modifications made as needed.
4. For women who are seen by a health care professional for the first time in labor and who have either not received prenatal care or have previously tested negative, but have not been

tested for HIV infection during the current pregnancy, education about HIV infection and maternal HIV testing are recommended during the perinatal period.

5. For newborns whose mother's HIV serostatus was not determined during the recent pregnancy or the postpartum period, the infant's health care provider should educate the mother concerning the potential benefits of HIV testing for her infant and the possible risks and benefits to herself of knowing the child's serostatus and recommend HIV testing for the newborn.
6. In the absence of parental availability for consent to test the newborn for HIV antibody, procedures need to be established to facilitate the rapid evaluation and testing of the infant.
7. The health care provider for the infant needs to be informed of maternal HIV serostatus so that appropriate care and testing of the infant can be accomplished. Similarly, if the infant is found to be seropositive when maternal serostatus is unknown, the health care provider for the child should ensure that information about the serostatus and its significance be provided to the mother and, with her consent, to her health care provider. The mother should receive appropriate referral to adult HIV-related services.
8. Comprehensive, HIV-related medical services should be accessible to all infected mothers, their infants, and other family members.
9. The Academy supports legislation and public policy directed toward eliminating any form of discrimination based on HIV serostatus.

PROVISIONAL COMMITTEE ON PEDIATRIC AIDS, 1994 TO 1995

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TESTIMONY
U.S. HOUSE OF REPRESENTATIVES
HEALTH SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
OF THE
COMMITTEE ON COMMERCE

by
W. Shepherd Smith
President
Americans for a Sound AIDS/HIV Policy

May 11, 1995

Thank you, Mr. Chairman, and members of this Committee for having a hearing which we believe will result in saving the lives of many young Americans.

I would like to preface my remarks by saying that I hope the attention given this subject will be serious and adequate, but will not take away from the reauthorization of the Ryan White Care Act that has already been before this Committee. If this means a separate bill for prenatal or infant testing, then we hope that is considered rather than any delay in Ryan White reauthorization. Secondly, Congressman Ackerman should be congratulated for bringing attention to this issue, as well as the Committee Chairman for agreeing to hearings on this critical issue so early in the 104th Congress.

When we formed in 1987, we quickly saw that HIV would affect the traditional family as well as the communities that it had heavily impacted by that point in time. In 1988 we began a Children's Assistance Fund to help families affected by HIV/AIDS, which has grown exponentially. This past year we helped over 8,400 children and families in one way or another, and expect this number to grow significantly higher in 1995. Our experience with infected infants and young people is regrettably very extensive.

Since its inception we have spoken out against the policy of blinded infant testing, arguing that many of the infections caused by this policy were totally unnecessary and completely avoidable. Women who were unaware of their HIV status who carried newborn uninfected infants home could subsequently breastfeed their child and transmit HIV. Had mothers known of their status, not only could many of these infections been avoided in the past, but these same women could have received medical care for themselves and reduced the risk of transmission of the virus to their future sexual partner or partners.

Regrettably we have an epidemic of ignorance that has been perpetuated by such policies which center nearly exclusively on the right of privacy of the infected individual at the exclusion and expense of the rights of those who are uninfected. It is

critical today in light of the 076 study showing that we can reduce infection rates among newborns from 26 percent to 8 percent that we make it a standard of care for women who are expecting to routinely be tested for HIV, along with the many other diseases they are presently tested for. They should, of course, be informed that this test is being performed and be given an understanding of the significance of the test if they so desire.

Further, for those who choose not to be tested, we feel they should have the opportunity to opt out for ignorance if they wish. In so doing, however, we would ask that they sign a form stating that they were offered a test but refused. By signing, should there be any complications resulting from HIV infection of either themselves or their child, they would release the physician who offered the HIV test from any future liability regarding this disease. It would be unfair to the physician for people to come back after the fact and argue that they should have been tested when they originally were given the opportunity and subsequently refused. This should not be interpreted to mean any physician is released from providing appropriate future care to a woman or her child should it subsequently be learned she is infected.

There has been debate as to whether such a program should be mandated or should be done voluntarily. Early in this epidemic many people believed, and certainly all of us hoped, that by providing excessive confidentiality and privacy protections to individuals at risk for HIV an environment would be created whereby people would voluntarily come forward to be tested. Certainly this was argued in legislatures throughout this great land, including the United States Congress; and we often heard that without such protections we would prevent people from coming forward and "drive the epidemic underground."

After a decade of voluntary programs that offered unprecedented protections to those who carried such a contagious disease we have witnessed incredibly disappointing results. As Dr. Philip Lee testified in your April hearing, perhaps 50 percent of the million people in the United States believed to be infected with HIV know their own HIV status. It is impossible to call such results anything but an abject failure. Most people today who are infected don't even realize they were exposed to an individual at risk for HIV, and are consequently unintentionally, unwittingly, and unknowingly infecting others. This is particularly true with women, especially those who are expecting children.

We must, and I emphasize must, turn this around since HIV is a preventable disease which can be stopped in its tracks if we get serious about making the diagnosis of it a routine practice in medicine and public health. It will not happen if we continue to issue recommendations and guidelines on a voluntary basis in certain settings. Such a policy has been tried, and failed.

It has been recommended by the Centers for Disease Control and Prevention, for example, that people who visit sexually transmitted disease (STD) clinics be tested for HIV. Today approximately half of the people going to STD clinics agree to be tested, and of that number only 40 percent return for their results. By capturing one in five of those individuals most at risk of HIV infection it is little wonder that the American public has lost confidence in our medical/public health community's response to limiting the spread of this disease.

As you will hear from others who testify, and as we have experienced through our work in this issue since 1987, this epidemic has spread far beyond those communities initially infected. Most women we work with have had to literally beg their physicians to be tested for HIV. Often this was done only after symptoms of disease developed because the physicians themselves did not believe this was either a heterosexual problem or could happen to someone in their practice. It has happened often and it will continue to happen (with the possible exception of high incidence areas) until we more routinely diagnose HIV.

A critical beginning point in respect to diagnosis in the medical setting today is of pregnant women since there is so much we can do for the unborn child. To not require that the testing of pregnant women become the standard of care is to say that the lives of young people are no longer important to our society. I for one cannot accept such a position, nor can anyone who is associated with our organization and the many friends we have who support and respect our efforts.

We, therefore, urge this Committee to pass legislation which will do the following:

- 1) Establish prenatal HIV testing as the standard of care in medicine;
- 2) Abolish the blinded infant study program by the CDC and apply those funds to women who are not covered by either insurance or medicaid for coverage of their prenatal HIV test;
- 3) Allow women who would like the option to not be tested to opt out for ignorance and require a waiver be signed releasing physicians of future liability;
- 4) Set aside sufficient dollars through the Ryan White Care Act to pay for the AZT treatment of the infected pregnant women who will not be covered by either private insurance or Medicaid; and
- 5) Require that any infant born to a mother whose HIV status is unknown be tested at birth.

If such legislation is enacted we will significantly reduce the scope of our future epidemic, significantly reduce the cost

to taxpayers of caring for infants and young people who would not have to be burdened by this disease, and at the same time allow the mothers who carry the virus to receive medical care and hopefully not infect others. Savings from such a program can release funds for other areas of need in future AIDS appropriations.

This can all be done without any additional cost to the taxpayer and in a way that continues to protect the confidentiality of both the mother and child. The medical and public health communities have performed exceedingly well throughout history in protecting the confidentiality of the health status of their patients. They have done this in respect to HIV and AIDS, as witnessed by the fact that we have reported over 400,000 cases of AIDS to the CDC without a single breach in confidentiality.

Before closing I would encourage this Committee to turn a deaf ear to those who sow fear, saying such things as "women will not seek care if they have to be tested." The theme of this argument has been used throughout this epidemic to block more routine diagnosis. For example, we were told in 1985 that testing of civilian military applicants would stop young people from entering an all-volunteer military. Not true, it never happened. Young people volunteered then, and continue to volunteer even though they know they'll be tested for HIV.

We were told reporting HIV and partner notification programs, now enacted in more than half our states, would stop people from coming forward to be tested and getting subsequent care. Again, not true. We were told that if doctors routinely diagnosed HIV in their practices, which nearly always requires consent, they would lose their patient base. Once more, not true. The fear of diagnosis for a relatively small number of people should not be the basis of sound AIDS/HIV policy development.

Nor can we any longer hide behind the excuse that we should not diagnose for fear that confidentiality may somehow be broken in the medical/public health community. We can no longer allow this excuse to kill young Americans. Such false arguments truly have driven the epidemic underground. We must begin to limit suffering in respect to HIV and AIDS through sound policy. This committee has the opportunity to put us on the right course through enacting legislation which will benefit future generations as well as women in the prime of their lives.

Thank you very much for your time and attention to this issue.