



Baby AIDS

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Foreward

Perhaps the single, most significant achievement in the battle against HIV/AIDS has been the discovery of medical interventions to nearly eliminate perinatal HIV transmission. Beginning with the 1994 announcement of the AIDS Clinical Trials Group protocol number ACTG 076 (076) that found the use of the AIDS medication zidovudine (ZDV) could dramatically reduce the transmission of HIV from an infected mother to her child, science has made it possible that extremely few babies will ever have to be born with HIV disease. Yet despite this promise, hundreds of babies continue to be infected with HIV every year in the United States. This raises some very important questions. Why is it that so many babies are allowed to have their lives cut short and die from AIDS when perinatal HIV infection can nearly be entirely prevented? What policies could have been – and should be – put in place to take advantage of the medical miracle that is available to save babies from AIDS?

Women and Children Increasingly Impacted by HIV

By the end of 1999, nearly 8,000 perinatally acquired AIDS cases had been recorded in the U.S., the vast majority (84 percent) of which are black and Hispanic children.¹ Most of the AIDS cases resulting from children born with HIV infection since 1997, however, have yet to be diagnosed or reported.² An estimated 120,000 to

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160,000 HIV-infected women are living in the United States, 80 percent of whom are of childbearing age.³ Approximately 6,000 to 7,000 HIV-infected women gave birth in the U.S. each

year from 1985 to 1995.⁴ And as women continue to comprise an increasing proportion of new HIV cases, more and more children are likely to be affected by the disease if no positive action is taken. Likewise more of the children and their mothers continue to disproportionately represent communities of color. African American and Hispanic women accounted for 80 percent of AIDS cases reported in U.S. women in 1999.⁵

During the early 1990s, before perinatal preventative treatments were available, an estimated 1,000 to 2,000 infants were born with HIV infection each year in the United States.⁶ The incidence of perinatally acquired AIDS peaked in 1992, and dramatically declined in the aftermath

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of the 076 study and the subsequent Public Health Service (PHS) recommendations made in 1994 and 1995 for routinely counseling and voluntarily testing pregnant women for HIV, and for offering ZDV to infected women and their infants.⁷ Without intervention, the mother-to-infant transmission rate would result in the birth of an estimated 1,750 HIV-infected infants annually in the U.S.⁸ Today – despite the fact that perinatal

transmission can be nearly eliminated – the Centers for Disease Control and Prevention estimates that 300- 400 babies continue to be born with HIV infection each year in the United States.⁹

Many Women are Still Not Tested, and Thereby Denied Care for Their Children and Themselves

In response to 076, the Centers for Disease Control and Prevention issued recommendations more than a year later, in 1995, requiring all healthcare providers to counsel pregnant women about HIV and offer voluntary testing with informed consent. The CDC released revised draft recommendations for HIV screening for pregnant women in October 2000 that vary slightly, but maintain the emphasis of the 1994 recommendations. No other prenatal medical screening for any other condition required such extensive pre-test criteria to be performed. Studies and anecdotal reports have found that this “AIDS exceptionalist” approach to perinatal HIV prevention has hindered efforts to effectively identify all affected women and newborns. There is a patchwork of different approaches and results in the various states.

Most HIV-infected pregnant women are still not tested and remain undiagnosed according to the findings of a study that examined a voluntary prenatal HIV testing program in northern California. The voluntary approach only resulted in the diagnosis of 20 percent of the HIV-positive pregnancies between 1994 and 1998. “Our experience,” concludes Dr. Edgar J. Schoen and colleagues from Kaiser Permanente Medical Care



Program in Oakland, “confirms the desirability of not depending on voluntary prenatal HIV testing to prevent maternal-fetal HIV transmission.”¹⁰

One in five (19 percent) HIV-positive women were not diagnosed before giving birth in 1996 according to CDC data from studies conducted in Louisiana, Michigan, New Jersey and South Carolina.¹¹

A state law adopted by Indiana in 1997, requiring all physicians to counsel and offer every pregnant woman an HIV test, has had little impact with less than half receiving HIV tests.¹² Dr. Martin Kleiman, director of pediatric infectious diseases at the Indiana University School of Medicine said that despite the law, for half of the babies who enter Riley Hospital for Children, there is no record of whether the mother has been tested for HIV.¹³

Tennessee, likewise, enacted a law in 1998, requiring all pregnant women be offered HIV tests. Last year, however, there were roughly 70,000 births statewide, but doctors notified the state of offering HIV tests to only 9,314 women during the first nine months. Of the roughly 15,000 births in Shelby County, Tennessee, doctors reported offering tests to only 1,248 pregnant women.¹⁴

Only 38 percent of pregnant women enrolled by Anthem Blue Cross and Blue Shield in Kentucky received prenatal HIV testing in the state in 1998, even though the cost of the test is covered by the insurer.¹⁵

“The median percentage of prenatal patients screened for HIV was only 10 percent,”

according to a study in Minnesota. Just 43 percent of physicians routinely recommended universal HIV screening for prenatal patients according to the researchers.¹⁶

Only a third of obstetric practices in Vermont and New Hampshire report testing 95 percent of their pregnant patients for HIV. Thirty-seven percent of these practices had HIV testing rates no higher than 50 percent.¹⁷

“the number of children born with HIV, . . . continues to be far above what is potentially achievable” . . .

Due to barriers and misperceptions, about 30 percent of women are not tested during pregnancy, according to a study published in the May 2001 issue of the *American Journal of Public Health*. “This study suggests that the U.S. health care system is falling short,” according to the authors who note “it supports the need to increase HIV testing if HIV infection is to be eliminated among U.S. children.”¹⁸

In Virginia, over 4,000 pregnant women receiving prenatal care in public health clinics did not receive an HIV test in 1997. This is more than one quarter of the 15,160 who received care in Virginia’s 32 health districts.¹⁹

One in five, or about 2,030, pregnant women in Delaware are not tested for HIV during pregnancy according to Dr. Ulder J. Tillman, the Director of Delaware’s Health and Services.²⁰



More than one in four (28 percent) pregnant women were not tested for HIV in inner city Chicago. Practitioners did not document whether testing was offered in almost 20 percent of the women. Of those women who were screened, 3.5 percent tested positive for HIV.²¹

Likewise, more than one in four pregnant women (28 percent) were not tested for HIV in a study conducted in San Francisco. Sixty-nine percent of patients, however, said that prenatal testing should be routine. The researchers

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conclude "proponents of elective testing should re-evaluate the assumption that patients view HIV testing differently from other prenatal tests for which separate written consent is not required."²²

According to these studies and anecdotes, between 26 and 62 percent of pregnant women are not being tested for HIV. Most alarmingly, depending which state one looks at, 12 to 80 percent of pregnant women who are HIV-positive are not tested, and therefore go undiagnosed and untreated. This increases the number of children who will become infected during or after birth. The CDC has conceded "the birth of every HIV-infected child is a sentinel health event signaling a missed prevention opportunity."²³ Clearly, far too

many women and infants are being denied optimal medical care under the CDC's own recommended approach.

The Institute of Medicine (IOM) has echoed this observation, stating "the number of children born with HIV, however, continues to be far above what is potentially achievable," and "more children than necessary continue to be born with HIV infection."²⁴

What Approach Will Save Mothers and Babies?

Few would argue today that relying on voluntary prenatal HIV testing is the answer. This approach has not been an effective policy to identify all women and children who need medical intervention and, therefore, has failed to maximize prevention opportunities.

Of the 449 children identified with perinatally acquired AIDS born in 1995-1997, 35 percent had mothers who were not tested for HIV before birth.²⁵ Roughly 15 percent of HIV-infected pregnant women receive no prenatal care.²⁶ And only 47 percent of women with HIV receive "adequate" prenatal care according to researchers.²⁷

"Newborn children are routinely tested for errors of inborn metabolism and other problems. Although most of the outcomes are rare, a positive test result triggers interventions that benefit both mother and child, and these efforts have been responsible for substantial improvements in health and well-being," according to the IOM. Furthermore, "these tests are well accepted, and seen to clearly benefit the women and her child."²⁸



The IOM outlines five criteria that must be met before newborns are screened for a disease. The disease must be both well defined and severe enough to justify screening in large numbers; the cost of the test must be reasonable; an accurate method of testing must exist; treatment must be available; and medical management facilities capable of confirming diagnosis and providing treatment must exist. Application of these five criteria to HIV leads to a conclusion that universal HIV screening for newborns is justified.²⁹

Every state requires newborns to be tested for a number of diseases and conditions. All states have mandatory newborn screening for phenylketonuria (PKU) and hypothyroidism. Most also routinely test for galactosemia, and 41 test for sickle cell disease.³⁰ None of these are as prevalent or deadly as HIV. Yet only two states—New York and Connecticut—require newborns to be screened for HIV. It would seem logical that babies should also be screened for HIV, particularly if the serostatus of a mother is unknown.

Has Routine HIV Testing Been Successful?

Since February 1997, New York has required HIV testing of all newborns. “Universal newborn HIV testing has resulted in the identification of all HIV-exposed births” in the state according to Dr. Guthrie S. Birkhead, Director of the New York Health Department’s AIDS Institute. Furthermore, “newborn testing has allowed hospital and health department staff to ensure that over 98 percent of HIV positive mothers are aware of their HIV status and have

their newborn referred for early diagnosis and care of HIV infection. In less than two percent of cases have women not been located to receive newborn HIV test results and have their HIV-exposed newborns tested for HIV infection,” according to Dr. Birkhead.³¹

Just under 1,000 HIV-infected New York women gave birth in 1998. Approximately 16 percent of these women did not receive prenatal

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HIV counseling and testing. Therefore, between 100-160 women may be learning their HIV status for the first time from testing conducted in the delivery setting.

In October 1999, Connecticut enacted a Baby AIDS law requiring universal HIV screening of all pregnant women and newborn HIV testing if no documented HIV test is on file for a woman before delivery.

Two studies presented at the 2001 annual meeting of the American College of Obstetricians and Gynecologists proclaimed the law a success.

Dr. Urania Magriples of Yale University in New Haven, Connecticut, said that since the law was enacted, a much greater percentage of women coming to Yale’s high risk pregnancy clinic are getting tested for HIV. Before the law, “only 38.9



percent of [pregnant] women were tested for HIV, but after the law 91 percent of women were tested,” she said. “I was originally opposed to this law because I thought it was coercion, but it works,” Magriples conceded. The law, she explains, actually “appeals to the maternal instincts in these women to protect their babies.”

“The birth of every HIV-infected child is a sentinel health event signaling a missed prevention opportunity.”

In the second study, Dr. William Cusick of Stanford Hospital in Connecticut studied the effect of the law during its first 10 months of implementation. Seven women were identified as HIV positive and two additional cases – a husband and a child – were identified after a positive test result. Without the testing requirements, Dr. Cusick acknowledges “we would have missed six of these nine cases.” “The results of our study demonstrate that the law is working exactly as intended,” he said. “So far all of the children are fine and we’ve followed them out for 12 months now,” Dr. Cusick noted.³²

Additional Benefits to Newborn HIV Screening

HIV diagnostics today offer noninvasive rapid testing that can help prevent perinatal transmissions. In addition to preventing babies from becoming infected with HIV during delivery, newborn screening offers many other benefits.

In most cases, children born to HIV infected women will not become infected during gestation or delivery, although they will carry detectable antibodies to the virus for some time. Those babies with infected mothers who are fortunate enough to escape HIV before and during delivery are still at risk for HIV if the mother breastfeeds. Studies have reported breast feeding transmission rates of 10 to 20 percent.³³ It is extremely tragic for a baby to escape infection only to become unknowingly infected by a loving, yet unsuspecting, mother via breastfeeding. Yet it continues to occur.

Newborn testing also offers additional hope to those babies who are infected. With knowledge of a child’s HIV status, appropriate medical care can protect and enhance the child’s health, and thereby prolong and improve life.

Pneumocystis carinii pneumonia (PCP) is the most common opportunistic AIDS related infection. The average survival time of a child who contracts PCP is one month. A study in *The New England Journal of Medicine* showed that two-thirds of children who developed PCP did not receive the disease-preventing prophylaxis because the physicians and families did not know the children were HIV-positive. “If infection is to be prevented, infants exposed to HIV must be identified earlier and prophylaxis must be offered to more children,” the researchers stated.³⁴

Research reported in the *American Journal of Public Health* showed that Vitamin A supplements alone will help infants with HIV fight off dangerous diarrhea, rashes, respiratory infections and other illnesses that could lead to death. This is a very inexpensive treatment with significant results.³⁵



Furthermore, triple combination AIDS therapy, highly active antiretroviral therapy (HAART), can significantly improve the survival of children infected with HIV. The drug “cocktails” have proven to reduce death rates and improve the quality of life of children with HIV. “The effectiveness in infants and children is at least similar, or even greater, than observed in adults,” according to researcher Patrizio Pezzotti of the University of Florence in Italy. The risk of death was 23 percent lower in children on monotherapy (one drug), 30 percent lower with double combination drugs and 71 percent down with standard triple drug therapy when compared to children who receive no antiretroviral drugs.³⁶

Studies have also concluded that newborn HIV testing saves money. “Annual routine newborn HIV testing would encompass 3.8 million infants, identify 1,061 infected mothers, avoid 266 newborn infections, and would cost \$7,000 per life-year gained” in the United States according to a study published in the *Journal of Acquired Immune Deficiency Syndromes*.³⁷ The average total lifetime charges for care of children with HIV infection is estimated at \$491,936.³⁸ The researchers concluded that routine testing of newborns is, therefore, “cost effective.”³⁹

A study in Chicago found that the universal HIV testing would result in fewer infected newborns and save the city nearly \$270,000 annually.⁴⁰

Newborn HIV Testing is Widely Supported

Newborn testing is supported by the medical community, by the elected branches of the federal government and, overwhelming, by the public.

The American Medical Association, the nation’s largest and most respected doctors organization, endorsed mandatory HIV testing of all pregnant women and newborns in 1996. “We have learned enough about the disease to know that the differences in those who are treated versus those who are untreated cuts by two-thirds the risk to the unborn child,” said Robert E. McAfee, an AMA trustee and former president.⁴¹ Surgeon

“We have learned enough about the disease to know that the differences in those who are treated versus those who are untreated cuts by two-thirds the risk to the unborn child”

General C. Everett Koop, M.D., stated that “as a former public health officer, I certainly approve of testing of newborns and believe that the information should be available to their parents and caregivers. I think this is the only sensible way to deal with the problem of HIV itself, but also would have the beneficial effect in the further transmission of the disease of AIDS.”⁴²

In 2000, the Congress passed without dissent, and President Clinton signed into law, the Ryan White CARE Act Amendments which contained a provision encouraging all states to enact newborn testing policies. States which pass such laws would be eligible for up to \$4 million in federal funds to support state efforts to reduce perinatal HIV transmission. “This amounts to a federal endorsement of universal HIV newborn testing as



a routine practice,” according to Congressman Tom A. Coburn, M.D., the bill’s author and a practicing physician who has delivered AIDS babies.⁴³

A 1995 poll of New York voters found four out of five respondents saying that mothers should be told the HIV status of their newborns. “The poll shows that the public’s attitude is to err on the side of saving as many babies as possible,” explained the Times Union newspaper. Support “runs across virtually every subgroup of those polled.”⁴⁴ Nearly nine in 10 participants in a 1996 *USA Weekend* poll said they favored mandatory HIV testing of all pregnant women.⁴⁵ A scientific survey published in the January 2001 issue of *Obstetrics and Gynecology* found that 84.3 percent of women believe all pregnant women should be tested for HIV and three out of five felt such testing should be legally mandated.⁴⁶

Editorial boards across the nation have echoed these same sentiments. *The Washington Post* has editorialized that “while counseling and voluntary testing are fine, all infants whose HIV status is unknown should be tested at birth and the results made known to parents, guardians and primary medical care givers.”⁴⁷ *The Chicago Tribune* writes that newborn testing “would allow for quick treatment of infected babies. Some political groups have tried to make the testing of women and infants for the AIDS virus a privacy issue, but they are wrong. It is first and foremost a public health issue – one that affects the lives and well-being of the most vulnerable among us.”⁴⁸ *The New York Times* “has long endorsed mandatory tests for the newborns” because it is “the best solution” to “insuring that all infected babies are identified for monitoring and treatment.”⁴⁹ “To save the babies we need to know their HIV status at

birth, and that of their mothers during pregnancy,” writes the *Wall Street Journal*, then asking, “how did the American system arrive at a point where it discovers it can save HIV-infected babies and then decides not to?”⁵⁰

The Arguments Against Newborn Testing

One must wonder why, with the obvious significant benefits and widespread support for newborn testing, such a program has not been recommended by the CDC or implemented nationally.

Over the past decade, newborn testing legislation has been introduced nationally and in numerous states. But, in nearly every case, AIDS activists have successfully derailed or fundamentally altered the underlying proposal with a set of unfounded and unproven claims. These arguments are:

- ◆ *Mandatory newborn HIV testing will deter women from seeking prenatal care and thereby, drive the epidemic underground.* “I feel sure we are going to see some women completely freaking out, committing suicide and running away from the whole situation,” predicted Terry McGovern of the HIV Law Project.⁵¹ The opposite has been the end result. New York’s “Baby AIDS” law has corresponded with an increasing number of pregnant women both receiving prenatal care and HIV testing. A CDC funded study “found higher voluntary prenatal testing rates... after implementation of mandatory newborn HIV testing.”⁵² “Rates of participation in prenatal care in New York



State... have been increasing gradually over recent years,” according to Dr. Birkhead who notes there has been “no [negative] detectable change” in prenatal participation trends “that might be related to the newborn testing program.”⁵³

- ◆ *Testing all newborns would be extremely expensive and would divert scarce resources away from other more effective interventions.* As previously noted, studies have found conclusively that universal newborn testing is the most cost effective intervention. Likewise in Connecticut, HIV testing rates for pregnant women jumped from 38.9 percent before the law to over 90 percent after the law was enacted.⁵⁴
- ◆ *There are few health benefits to newborn testing, in effect, it is too little too late.* This could not be further from the truth. With prompt diagnosis and treatment, within 48 hours of birth, HIV infection can be prevented. Other at risk babies can be prevented from unknowingly being infected via breastfeeding. And for those children who are infected, appropriate treatment and proper medical monitoring can prolong and improve health outcomes.
- ◆ *Voluntary testing of pregnant women is the best approach to reducing perinatal HIV transmission.* At least 15 percent of HIV-infected pregnant women are not tested. Many do not receive appropriate prenatal care, some receive no prenatal care and others may simply refuse to be tested. It is not an “either/or” proposition,

rather both approaches should be utilized. Prenatal screening provides for early intervention and newborn testing ensures that all babies are identified.

Clearly, far too many women and infants are being denied optimal medical care.

- ◆ *Testing is unreliable and may result in the treatment of uninfected children with highly toxic medications.* Rapid HIV tests can produce results in an average of 10 to 30 minutes. The sensitivity and specificity of these rapid assays are comparable to other HIV diagnostics. A negative rapid test does not require further testing, and negative results indicate the absence of HIV infection. There is a slim possibility that some tests may produce a “false positive” for HIV. Therefore, a reactive rapid test must be confirmed by a supplemental test. Results from a confirming test to the rapid return may be available within 12 hours of the infants’ birth.⁵⁵ Studies have yet to show that ZVD has caused any significant adverse health consequence to children. Regardless, a short course of ZVD over several hours is far less dangerous than risking the alternative.
- ◆ *Testing a newborn for HIV also reveals the HIV status of the mother, and therefore, violates the mother’s privacy, or her “right not to know her HIV*

status.” Unfortunately, this is the crux, and underlying agenda of many AIDS activists. The dogma that places privacy over all else, including saving lives of women and babies is based on fear and

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outdated ideology rather than reality or sound public health. No scientific data indicates that loss of privacy has ever been an outcome of newborn testing policies. Anecdotally, few, if any, mothers have voiced the opinion that protecting the health of their baby jeopardizes their own personal rights. “You can’t compare a baby’s right to medication against a woman’s right to confidentiality,” explains Shelly Harrington – an HIV-positive mother of an HIV-positive teenager – who supports HIV testing for both pregnant women and newborns.⁵⁶ Hiding behind privacy will not save lives and it will not cure AIDS.

These arguments have either been discredited or remain unsubstantiated and run contrary to the existing medical, political, and popular sentiment regarding newborn HIV testing. “With New York

clearly demonstrating that mandatory testing of newborns saves lives without endangering women, the argument should have been settled. But opponents are so steeped in ideology that facts don’t matter,” explains Wesley J. Smith, a well-regarded author on medical ethics.⁵⁷

Conclusion

Unquestionably, the optimal method to prevent perinatal HIV transmission is to identify every infected pregnant woman as early as possible in her pregnancy and provide her with proper prenatal care and prophylaxis. Most women, when offered, will accept an HIV test.⁵⁸ Unfortunately, a significant proportion of HIV-infected mothers do not receive appropriate, or any, prenatal care and thereby go undiagnosed and untreated. Routine newborn screening provides a safety net to ensure that no HIV-exposed child is left to slip through the cracks and become needlessly infected. Such a policy also ensures that infected mothers who were previously unaware of their serostatus are given an opportunity to access medical care.

The New York program “has proven to be very effective in increasing prenatal testing rates while providing a safety net to facilitate early treatment for HIV positive newborns and their mothers who were unaware of their serostatus prior to delivery,” according to Dr. Antonia C. Novello, New York’s Commissioner of Health and former U.S. Surgeon General.⁵⁹

This approach unquestionably has proven to be the single most successful baby AIDS prevention policy. It is more cost effective than other approaches and is the only one to identify all



those who are infected or at risk. The New York Baby AIDS law, therefore, offers a paradigm that the CDC, other states, and other countries must embrace if perinatal HIV transmission is ever to be eliminated.

“The success rate is phenomenal,” New York Assemblywoman Nettie Mayersohn, the author of the state’s Baby AIDS law proudly proclaims. She believes that “eventually it’s going to happen” nationally. “It’s just a question of how long it’s going to take and how many [babies’] lives we are going to lose before we reach that point.”⁶⁰

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Notes



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