THE WASHINGTON POST
FRIDAY, MAY 3, 1996

Mom's Privacy or Baby's Welfare?

FOR MORE THAN a year, Congress has failed to provide guidance on the divisive matter of testing mothers and newborn babies for HIV infection. This week an agreement was reached that is less decisive than it should have been but at least is an improvement over current practice.

Many people working to control AIDS believe as follows: Nothing should be mandatory; pregnant women should be counseled about the disease and its potential effect on their babies, but only if they voluntarily agree; no tests should be required of anyone; and the results of tests taken as part of a sample used for statistical purposes should remain secret—even from the mothers. Others, admittedly more concerned about the babies' welfare than the mothers' privacy, argue 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. They are right.

Infants who are HIV positive need a different kind of care. They should not be breast-fed by an HIV-positive mother, for example. They should not receive routine vaccinations of the same kind and on the same schedule as unaffected children. Great care must be taken to protect them from other infections, such as pneumonia and tuberculosis. And foster parents, who care for many of these children, must know about this special problem. And while it recently has been proved that AZT therapy given before and during labor to infected mothers and thereafter to their babies cuts the risk of HIV infection by two-thirds, some variation of this treatment given only to the baby after birth may prove beneficial. Balancing all this against a mother's right to privacy, we believe, makes a choice easy.

Instead, there is a compromise. All pregnant women—not only those in high-risk groups—are to be offered counseling and testing. And the states are to compile and report statistics on mother-to-baby HIV transmission to the Centers for Disease Control. That's all fine so far. But it does not deal with the problem of mothers who do not want to know their HIV status and will object to the testing of their children. Congress puts that off until the year 2000, when the testing of infants will become mandatory unless the rate of transmission is cut in half, or if 95 percent of pregnant women receiving prenatal care have agreed to be tested. As for the HIV-positive babies born between now and the end of the century—between 6,000 and 7,000 a year, if current rates continue—some will receive the medication and special care they need. Unfortunately, many others whose status will be unknown will not be helped at all. That's what's so wrong with the compromise.

Hoop Dreamers, in a Hurry

ALLAN IVERSON, an electrifying performer for Georgetown University's basketball team the past two seasons, is leaving college early to play in the National Basketball Association. That isn't unusual in most of college ball these days, but it's unheard of at Georgetown, where John Thompson had never "lost" a player to the pros before graduation.

Mr. Iverson may or may not make it in professional basketball. Far more important is the question of whether John Thompson—or those who think like him—can continue to make it in the world of college basketball while doing things as he does: graduating young men capable of making a good living, and good lives, without a basketball in their hands.

Mr. Thompson joked on Tuesday that this early departure might make his recruiting easier, since his insistence on getting an education had, in the past, frightened away many good high school players who didn't want to commit to staying the course for a college degree. But there was a disturbing significance to Mr. Iverson's action, coming as it did just as another wave of freshmen, sophomores and even a high school student, were offering themselves up for the pro draft.

Some of these players are, no doubt, enticed by the exaggerated promises of agents who hope to make money off them. Others probably are acting on a pretty good calculation as to what course of action will ensure them the best lifetime income. But the overall effect of this annual coming-out party is to make college basketball look more and more like a way station where the smart guys spend as little time as possible before turning pro. The trouble is that for most college players, that isn't going to be an option; they'll never play in the NBA.

They do, however, have the opportunity to earn a diploma. This fact has been the center of John Thompson's program. He has been made out to be a sort of saint in the basketball world. He isn't. He can be imperious, intemperate and difficult, and he makes a lot of money out of the game. But over the years at Georgetown, he has established a record for integrity and genuine concern about those who play for him—and a reputation for being serious about academics. He follows the careers of his former players closely, and is as proud of those who are making it in business, education, the law, as he is of Patrick Ewing and Dikembe Mutombo in the NBA. Most important, he has combated the image of college players as semi-students and mercenaries. Short-term or long, the better future for most of the kids who play the game lies with a wider acceptance of that approach.

What's News—

Business and Finance

* * *

STOCK AND BOND PRICES plummeted on news that the nation's economy surged at a 2.8% annual rate in the first quarter. The yield on the 30-year Treasury bond leapt to 7.05%, its first close above the 7% level in a year. The Dow industrials sank 76.95 points to 5498.27, their steepest drop in a month. Traders braced for today's report on April employment. Employment figures have battered financial markets in the past two months.

(Articles on Pages A2, C1 and C15)

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The Energy Department said record recent gasoline imports into the U.S, primarily from Europe, are expected to bring motorists some relief from the surge in pump prices.

(Article on Page A3)

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A high-tech merger boom is accelerating, particularly among hardware and software makers racing to exploit explosive communications markets but who can't afford to take the time to build those businesses internally.

(Article on Page A3)

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An Alliant Techsystems unit is under criminal investigation for allegedly overcharging the Pentagon on missile-production awards, according to people familiar with the matter.

(Article on Page A3)

* * *

GM is likely to set up a used-car program to reduce anxiety over quality and pricing, but the move may push prices even higher. Ford is rolling out pilot programs while Chrysler says it's considering a similiar move.

(Article on Page A4)

* * *

The UAW is expected to press GM for wage increases and job-security guarantees even though the auto maker maintains it needs union concessions to remain competitive.

Top GM and UAW officials are negotiating the possible reinstatement of a Lordstown, Ohio, union official who was fired over fraud charges.

(Articles on Page B3)

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MCA selected Loews as its partner in the $600 million development of two luxury hotels in Orlando, Fla., in an effort to break Disney's lock on the Orlando hotel and convention market.

(Article on Page B12)

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A senior Intel official said prices for personal computers using the company's top-of-the-line Pentium Pro microprocessor are expected to fall below $3,000 in the next few weeks.

(Article on Page B4)

* * *

Astra USA in investigating allegations that its former chief executive and other top managers used corporate funds for personal expenses, people familiar with the matter said.

(Article on Page B11)

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Turner Broadcasting is weighing the sale of its troubled Castle Rock Entertainment film-making unit, according to people close to the company.

(Article on Page B12)

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World-Wide

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THE SENATE APPROVED a bill to discourage illegal immigration in a 97-3 vote.

The bill would significantly increase law-enforcement efforts by authorizing the hiring of 4,700 more Border Patrol agents and 600 more INS employees. It also provides for pilot programs to help employers identify undocumented workers. It must now be reconciled with a House version that contains a provision that would allow states to bar the children of illegal immigrants from public schools. (Article on Page A14)

A House chairman set a vote next week on citing the attorney general and White House counsel for contempt in a battle over travel-office documents.

* * *

Clinton held talks with a bipartisan group of moderate lawmakers in an effort to take the offensive in the budget battle. Meanwhile, details began to emerge on a revised six-year plan the GOP is to unveil next week. The two sides are far apart, and election-year pressures make chances for an deal this year remote. (Article on Page A14)

* * *

U.S. Marines stood ready to go ashore in Liberia's capital if renewed factional fighting threatened the U.S. Embassy, and U.S. warships continued their show of force. Fighting yesterday centered on a bridge near the embassy in Monrovia. Control of the bridge by rebel forces would allow them to bring more fighters into the city.

* * *

A card found in Terry Nichols' home paid for more than two dozen calls to fuel suppliers, chemical distributors and a big explosives manufacturer in the months before the Oklahoma City bombing, the Dallas Morning News said phone records show. Most of the calls were made in a three-day period in September 1994, the newspaper reported.

* * *

Truckers boycotted the ports of Los Angeles and Long Beach, cutting in half the shipment of goods to rail terminals and final destinations. The ports handled $157 billion in goods last year and account for 25% of all U.S. container traffic. Low pay and rising pressures brought by the ports' growth are driving the boycott. (Article on Page A2)

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Federal agents arrested dozens of suspected drug traffickers and said the raids, and earlier ones, have broken up a nationwide Mexican-Colombian cocaine ring. Among those arrested were a New York policeman and a National Guard sergeant. Clinton called the sweep "a big victory."

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South African police raided a workers dormitory controlled by Zulu nationalists in Durban and arrested nine men suspected of taking part in an attack last week on the Zulu royal family. A standoff then developed when about 400 armed Zulus surrounded the police station and demanded their release.

* * *

Militants in Montana rejected a request by FBI agents for a meeting tomorrow. In a letter to the group, the FBI said it would take "whatever action it deems necessary" if the antigovernment militants fail to show any willingness to end to a 5½-week standoff.

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U.S. health officials said asthma deaths among people under age 24 more than doubled from 1980 to 1993. Blacks in some age groups were six times more likely than whites to die of the disease. A study author wasn't sure how to explain the findings.

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Rep. Waldholtz's husband was charged with bank fraud involving a $3 million check-kiting scheme. Prosecutors said the 27-count indictment is part of a broader investigation into the couple's finances. The Utah Republican has filed for divorce.

* * *

Britons voted in local elections widely predicted to produce heavy losses for Prime Minister Major's Conservative Party and increase pressure for early national elections. Polls predicted the Tories would lose half the 1,200 municipal seats they hold.

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Millions of Indians cast ballots in the second round of parliamentary voting, and eight were killed in election-related violence. Most died in the northern state of Bihar. Yesterday was election day for one-third of India's electorate of 590 million.

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Swiss banking officials signed an agreement with Jewish leaders to improve access to secret files in searches for records of unclaimed deposits by Holocaust victims. The agreement also creates a central organization people checking claims can contact.

* * *

Died: Herbert Brownell, 92, Eisenhower's attorney general during the 1957 Little Rock, Ark., school-desegregation battle, Wednesday, in New York, of cancer.

British Telecom's merger talks with Cable & Wireless were broken off, stymied by uncertainties over price, regulation and corporate strategy.

(Article on Page B4)

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Delta estimated that its new pilots' contract will produce about $760 million in savings over four years, less than expected but still acceptable.

(Article on Page B3)

* * *

Markets

Stocks: Volume 441,051,910 shares. Dow Jones industrials 5498.27 off 76.95; transportation 2192.79, off 16.57; utilities 207.66, off 2.30.

Bonds: Lehman Brothers Treasury index 6063.37, off 84.94.

Commodities: Oil $20.88 a barrel, up 5 cents. Dow Jones futures index 156.58, off 0.38; spot index 152.65, off 1.05.

Dollar: 104.40 yen, off 0.93; 1.5285 marks, off 0.0075.

THE WALL STREET JOURNAL
FRIDAY, MAY 3, 1996

"All the News That's Fit to Print"

The New York Times

New York: Today, sunny, breezy. High 65. Tonight, a few showers late. Low 51. Tomorrow, partly cloudy, a few showers. High 68. Yesterday, High 61, Low 48. Details, page C13.

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SUNY Chancellor Resigns Post After Battling Pataki's Trustees

Board's Rebuff Over Provost Had Caused a Rift

By JAMES BARRON

After months of tension and disagreement over the direction of the State University of New York and Gov. George E. Pataki's plans to streamline SUNY, the Chancellor of the 64-campus, $5 billion system turned in his resignation yesterday.

The Chancellor, Thomas A. Bartlett, was appointed in October 1994 by the SUNY trustees while Mario M. Cuomo was Governor. He had been at odds with the seven trustees appointed since Governor Pataki took office in January 1995.

The trustees appointed by Mr. Pataki have increasingly wielded more power over policy issues and personnel matters, pressing to de-emphasize SUNY's historical centralized approach to managing its far-flung operations. They have also favored giving each campus autonomy over crucial matters like tuition and academic standards.

A highly placed member of the university system's administrative staff, who spoke on condition of anonymity, said that what triggered Mr. Bartlett's departure was the failure of the SUNY trustees to approve his choice for provost on Monday. The provost would have been, in effect, Mr. Bartlett's second in command.

He had nominated Daniel Fallon, a veteran college administrator who is the chief academic officer at the University of Maryland and a former psychology professor at the State University at Binghamton, N.Y.

Mr. Bartlett said nothing beyond a short prepared statement, which urged SUNY not to lose sight of its strengths as it evolves in a time of financial and philosophical change.

"As it repositions itself to fit very new circumstances," he said in the statement, "it is vital to protect the founding vision of the State University of New York: broad access for students and national levels of educational quality. I believe it is incumbent upon the board of trustees to pick a chancellor that it will support with authority and commitment."

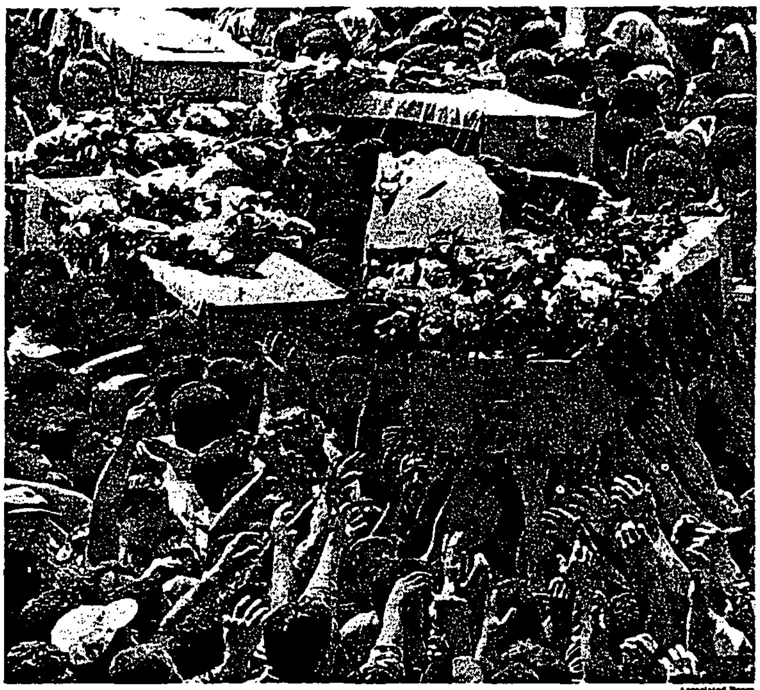
Mr. Bartlett said he had concluded that he was not that person.

"I have spent a great deal of time over the last several weeks thinking about what is best for the State University and how its interests are best served," he said. "I have decided that while I still feel very much committed to SUNY, it is best at this time that I step down as Chancellor."

Mr. Pataki issued a statement that praised Mr. Bartlett for serving "with distinction and professionalism." The Governor said Mr. Bartlett, a former chancellor of the Oregon university system who came out of retirement to take the New York job, had "helped to position our State University for increased success in the future."

In the last few weeks, Mr. Bartlett had made little secret of his differences with the SUNY board. One of the biggest problems was what role each should play. For example, in choosing a new provost, a chancellor typically has considerable latitude. But some trustees expressed interest in looking at several candidates rather than allowing Mr. Bartlett to

Continued on Page B5, Column 5



Associated Press

Lebanon Buries Victims of Israeli Shelling

Coffins were passed from hand to hand yesterday at a funeral near the United Nations camp where an attack on April 18 killed about 90 people who had taken refuge from an offensive against Islamic militants. Page A6.

BILL WOULD ORDER AIDS-VIRUS TESTING TO PROTECT BABIES

CONFERENCE AGREEMENT

Privacy Fears Are Raised, but States That Resisted Would Lose Some Federal Aid

By IAN FISHER

WASHINGTON, April 30 — House and Senate negotiators tentatively agreed today on a measure that would eventually require states to begin mandatory testing of newborns for H.I.V., the virus that AIDS, if health officials cannot reduce the number of infected infants by other means, people involved in the talks said tonight.

States that did not comply would risk losing Federal money provided under the Ryan White act, which provides hundreds of millions of dollars in Federal money each year for treatment of people with AIDS. The testing provision has been agreed to by House and Senate conferees ironing out differences in companion versions of the overall bill, Congressional aides and others said.

The provision would establish a complicated series of measures states would have to take, and it was not immediately clear if all of the details had been decided. But several people involved in the conference said the bill would take cautious but certain steps toward national of newborns.

The provision would apply only to women whose H.I.V. status is not known.

The question of mandatory testing has long been one of the most contentious AIDS issues, particularly among people who fear mandatory testing would violate the privacy rights of patients. The issue is particularly thorny when it comes to newborns. Studies show that steps taken before or at birth can substantially reduce *the rate* of AIDS transmission from mother to infant. On the other hand, because infected infants can be born only to infected mothers, an infant's test results could reveal the mother's medical condition, whether she wished to be tested or not.

New York is the only state that has addressed the issue in regulation. Like most other states, New York has routinely conducted anonymous AIDS tests on newborns, as a way of tracking the spread of the disease. For the first time, in regulations that go into effect on Wednesday, ers will be able to learn their in test results — and, by proxy, their own.

The agreement ironed out today in the Ryan White Comprehensive AIDS Resource Emergency Act would require doctors and other health care workers to advise pregnant women to be tested for H.I.V., a measure that advocates for people with AIDS have long pushed as an alternative to coercive mandatory testing. But testing of children born to mothers whose H.I.V. status is not known at birth would become mandatory if the number of infected children was not reduced by counseling alone by the year 2000.

Serious disagreement over the rest of the overall measure is consid-

Continued on Page D22, Column 3

Array of Opponents Battle Over 'Parental Rights' Bills

By PETER APPLEBOME

Congress and state legislatures around the country are becoming battlegrounds over politically charged "parental rights" bills, pitting conservative and religious-right groups seeking broader protections for parents against education, public health and liberal organizations who say such laws are major threats to children and schools.

The bills include the Parental Rights and Responsibilities Act pending in Congress and proposals for amendments to state constitutions that have been introduced in 28 states and are the subject of a referendum drive this year in Colorado.

The model language for the bills, adapted from a 1925 Supreme Court ruling and proposed by a "pro-family" group called Of the People, which is promoting such laws, states, "The right of parents to direct the upbringing and education of their children shall not be infringed." No such laws have yet been enacted.

In advocating such legislation, conservative Republicans, Christian groups and organizations like the Eagle Forum and Focus on the Family cite cases of children given counseling over the objections of their parents or exposed to sexually explicit materials in schools.

"What we're trying to insure through this legislation is very simple: that schools reinforce rather than undermine the values parents teach to our children in our homes, churches and synagogues," said Ralph Reed, head of the Christian Coalition, which supports the legislation. "The American people agree with us, and if Bill Clinton is faced with a situation where he gives in to extremist organizations on the left and vetoes this, he's going to have a serious election-year problem on his hands."

Mr. Clinton has had no comment on the Federal legislation. The pre-

Continued on Page B7, Column 1

Wages in U.S. Rose 1% in First Quarter

Wages and salaries advanced 1 percent in the first three months of the year — the fastest pace since 1991.

After years of concern about stagnant wages, the increase is the first sign that many workers are beginning to enjoy increases in pay that outpace the rise in the cost of living.

The Government report, combined with a separate private survey showing that consumer confidence improved in April, points to an economy gradually picking up speed.

But that pace has some analysts worried that inflation could accelerate. Indeed, an increase in wages, coming at a time when crude oil and grain prices have jumped sharply, could threaten to rekindle inflation, these analysts say, and prompt the Federal Reserve to keep a tight rein on credit by raising interest rates.

Business Day, page D1.

Democrats Outflank G.O.P. In First Campaign Skirmishes

By ADAM NAGOURNEY

WASHINGTON, April 30 — Senator Bob Dole fired the first shot last Friday afternoon: a single-page press release and letter to President Clinton demanding repeal of the 4.3-cent gasoline tax increase enacted as part of Mr. Clinton's 1993 deficit-reduction program. Mr. Dole, his aides said, would ride the issue through the coming week.

President Clinton responded to Mr. Dole's bullet with a cannon blast. Leon E. Panetta, the White House chief of staff, issued a statement urging Mr. Dole to join talks on balancing the budget. Mr. Clinton's campaign headquarters faxed out a stream of documents containing a 14-year history of gasoline tax increases and Mr. Dole's earlier advocacy of such increases.

By Monday, Mr. Clinton had moved to trump Mr. Dole by invoking the full power of the White House, announcing — in time for the evening news broadcasts, as his aides boastfully recounted today — that the Government would sell oil from the Strategic Petroleum Reserve in an effort to stem the price rises at the pump.

The recent skirmishes over the gasoline tax point to a growing disparity that Mr. Dole's aides and Republicans outside his organization are viewing with evident and increasing concern: While Mr. Dole is still grappling to lay the basic foundations of a Presidential challenge, the Clinton campaign is emerging as a formidable machine, able to draw at once on the power of the Presidency and an experienced and well-financed campaign apparatus.

With the primary season behind it, Mr. Dole's campaign is confronted with difficulties caused by a relative lack of experience among its staff (Mr. Dole has almost logged more time on the Presidential circuit than his senior staff combined), a bifurcated political existence that pulls

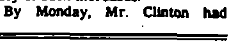
Continued on Page A16, Column 1

Back and Forth on Gas

Republicans pushed for repeal of a 1993 gasoline tax, blaming the Administration for higher pump prices. And in response to the President's move to tap Federal oil reserves, oil prices fell in futures markets.

Articles, page A16.

Doug Pensinger/Allsport



Associated Press

Unbridled's Song's groom, Martin Perales, left, sprucing his charge up yesterday before the horse tested a new shoe meant to help his ailing foot. Above, a farrier, Steve Norman, swabbing the foot.

INSIDE

Emphasis on Manufacturing

Mayor Rudolph W. Giuliani announced a plan to encourage new industry like the manufacturing of computer software. Page B1.

School Board Wins in Court

Chancellor Rudy Crew's efforts to remove corrupt school boards sustained a second defeat. Page B3.

Behind a Witch Trial

Although a Maine woman was convicted by her church of claiming to be a witch, what was really at issue was real estate. Page A12.

Derby Favorite May Miss Race and a Dream

By JOSEPH DURSO

LOUISVILLE, Ky., April 30 — Ernie Paragallo, a husky, ruddy man with bushy hair and a knack for picking horse talent, is no Kentucky *aristocrat. He is a "pinhooker" from* Brooklyn, a man who buys horses low and sells them high.

Not so long ago, a dream investment seemed to have him at the top of the horse racing business as the owner of Unbridled's Song, the favorite for Saturday's 122d Kentucky Derby and a son of Unbridled, winner of the 1990 Derby. But today, a sore left forefoot has compromised his colt's chances and left Paragallo and his trainer with the difficult decision of whether to run at all.

It is a crossroads that underlines all the financial risks and emotional pressures of trying to win America's most treasured horse race.

Among the questions facing Paragallo are these: Is the colt fit enough to run, let alone win? Should he risk damaging Unbridled's Song bloodstock value with a poor performance? Did his trainer make any mistake in treating the sore foot after the last race, the Wood Memorial at Aqueduct, three weeks ago? And, since a horse has just one chance, how important is it to win the Derby at any cost?

The stakes are high, especially for Paragallo, who normally deals with horses of far less quality. With a $1 million purse, the Derby will pay $600,000 to the winner and provide greater rewards in the breeding shed when a horse's racing career is over.

"If things go our way," said Jim Ryerson, who trains the colt, "I think we have enough days left to heal the injury, and he'll do fine. Maybe they won't, but at this point we are thinking optimistically."

They have no other choice. A final

Continued on Page B11, Column 4

Uncovered in a Harvard Library: Alcott's Unpublished First Novel

By LAWRENCE VAN GELDER

The manuscript of Louisa May Alcott's very first novel, all but unknown to scholars and written when the author was 18, has been found in the Houghton Library at Harvard University, where it was apparently miscatalogued a generation ago.

Discovered by two professors researching Alcott's letters and journals, the novel, titled "The Inheritance," was written in 1849 and tells the tumultuous tale of Edith, a poor orphaned Italian girl adopted by a wealthy English family.

The manuscript was apparently never offered for publication and was never mentioned in Alcott's journals, said Lane Zachary of the Zachary Shuster Agency in Boston, a literary partnership, which will be offering the work simultaneously to publishers and film companies for bidding on Monday. Ms. Zachary categorized "The Inheritance" as a young-adult novel.

"There is no record of it," said Ms. Zachary, who in 1994 negotiated the seven-figure sale of "A Long Fatal Love Chase," an Alcott novel rejected in the 19th century as too sensational to be published.

In some ways — the use of the name Amy and the close sisterly relationship between Edith and Amy,

Continued on Page C22, Column 3

Louisa May Alcott

THE NEW YORK TIMES
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Serious disagreement over the rest of the overall measure is consid-

Continued on Page D22, Column 3

Continued From Page A1

ered unlikely and it is expected to win passage in both houses of Congress.

Although influential AIDS organizations oppose mandatory testing, they are expected to endorse the overall measure in hopes of winning repeal of the testing provisions later.

Advocates for people with AIDS attacked the mandatory testing provision, arguing that it would violate the privacy rights of pregnant women. They said the requirement would fall heaviest on poor women who are afraid to be tested for AIDS.

Among other fears, the advocates say, these women worry that tests showing they carry H.I.V. might cause them to lose custody of their children or housing or other benefits.

Also, they said, many people fear that the test results would not remain confidential.

"It is relatively horrifying," Theresa McGovern, a lawyer and the executive director of the H.I.V. Law Project, a Manhattan advocacy group that intends to challenge the new regulations in New York.

Like many other advocates for people with AIDS, she said there are better ways to spend scarce money than on mandatory testing. "I wish this kind of attention and effort had been paid to getting prevention," she said.

But Representative Gary L. Ackerman, a Queens Democrat who has long advocated mandatory testing of newborns, said the testing process would conform to high standards of privacy. And, he said, concerns over a child's health outweighed a mother's absolute right to privacy.

"Morally, it's the right thing to do," he said.

He said that in 1993, the last year for which figures are available, there were 6,489 cases nationally of pediatric AIDS, including 1,651 in New York.

A positive H.I.V. test in a newborn shows only that the child's blood has the mother's antibodies. That means that the mother is definitely infected, but he said there is only a one-quarter chance that the virus will remain in the child's system, and that risk can be reduced with treatment. Requiring testing, he said, would allow mothers to get treatment and avoid other circumstances, such as breastfeeding, in which a child could possibly become infected after birth.

The proposed agreement is complicated, part of the roughly $700 million Ryan White AIDS legislation now being hammered out between the two houses.

According to a draft version, the compromise would require a two-segment process: mandatory counseling on its own, followed by mandatory testing.

Within several months of passage, doctors and other health care workers would be required to advise pregnant women to be tested, in accordance to guidelines drafted by the Centers for Disease Control and Prevention.

After roughly two years, the Federal Government would determine how well counseling on its own fared. States would be required to begin mandatory testing in two instances: if there was not a 50 percent reduction in the number of infected babies born, or if less than 95 percent of the women who were counseled actually received an AIDS test.

Senate Votes to Make Female Genital Mutilation a Federal Crime

By William Branigin
Washington Post Staff Writer

The Senate voted yesterday to make female genital mutilation a federal crime and to repeal a provision of the recently signed anti-terrorism law that restricts the ability of illegal aliens to enter the United States by claiming political asylum.

The votes were taken on amendments to a bill on illegal immigration being debated on the floor. Sponsored by Sen. Alan K. Simpson (R-Wyo.), the bill is aimed at cracking down on illegal aliens by strengthening the U.S. Border Patrol, stiffening penalties for alien smuggling and making it more difficult for illegal immigrants to obtain jobs and government benefits.

By a voice vote, the Senate approved an amendment by Sen. Harry M. Reid (D-Nev.) to criminalize the practice of circumcising girls by cutting off all or part of their genitalia. The painful ritual, often performed without anesthesia by medically untrained practitioners, has been imported to the United States in recent years by immigrants from Africa and the Middle East.

The amendment sets penalties of up to five years in prison and fines for those who perform female genital mutilation on girls under 18, a practice Reid described as "a horrible custom" that should not be permitted to take root in U.S. immigrant communities. In a compromise with advocates of more restrictive immigration policies, Reid agreed to withdraw language in the amendment that would have offered political asylum to women who claimed to be fleeing the ritual in their home countries.

In a highly publicized case, the Board of Immigration Appeals, the highest immigration court in the United States, is to hear arguments today in Falls Church on a bid for political asylum by Fauziya Kasinga, 19, who says she fled her native Togo to avoid genital mutilation.

By 51 to 49, the Senate yesterday approved an amendment to repeal a provision of the anti-terrorism bill that cracks down on asylum seekers who enter the country with false documents or no documents. That provision and a similar one in the Simpson bill would have allowed immigration officers at U.S. ports of entry to evaluate on the spot the asylum claims of illegal aliens and turn them back if they failed to demonstrate a credible fear of persecution in their home countries.

The amendment, sponsored by Sen. Patrick J. Leahy (D-Vt.), essentially preserves current law, which allows such claimants a lengthy process of judicial review. But the measure also gives the attorney general special authority to summarily "exclude" illegal aliens in situations of extraordinary migration.

In opposing the amendment, Simpson argued that it would "gut" an effort to reform a system that allows thousands of illegal aliens to enter or remain in the country by making fraudulent asylum claims, even though they may have been brought in by professional scam artists and presented false travel documents.

Simpson argued that those with valid asylum claims are far outnumbered by charlatans who are "gimmicking the system."

In another narrow vote, the Senate by 54 to 47 tabled an amendment to delete the bill's provisions for a pilot program to verify the employment eligibility of job seekers in states with high concentrations of illegal immigrants. The amendment also sought to eliminate a requirement that state driver's licenses and birth certificates meet federal document-security standards. Simpson, backed by Democrats Edward M. Kennedy (Mass.) and Dianne Feinstein (Calif.), argued that the provisions were vital to prevent illegal immigrants from obtaining jobs and benefits by using fraudulent documents.

AIDS Testing Compromise Is Reached

Hill Negotiators Agree On Pre-Natal Program

By Helen Dewar
Washington Post Staff Writer

House and Senate negotiators agreed yesterday to a new program aimed at encouraging pregnant women to be tested for the virus that causes AIDS but requiring mandatory testing of newborn infants if the voluntary effort fails.

Under the HIV testing compromise, tests would be required for newborns by the year 2000 for states that have not demonstrated success in testing pregnant women or in cutting the number of children born with parental-caused HIV infection.

The agreement broke an impasse over a House-approved proposition to require newborn testing that held up a five-year reauthorization of the Ryan White CARE program. Under the program, named after an Indiana teenager with hemophilia who died after contracting AIDS through a blood transfusion, seven years ago, $738 million in spending for treatment and support for AIDS victims has been appropriated for this year.

Senators, with support from physicians, governors and AIDS organizations, favored voluntary efforts over mandatory infant testing. One argument against mandatory testing of newborns was that it violated privacy rights; another is that the pre-birth testing of mothers is preferable because it lead to treatments that reduce risk of infection for their children.

"Medical technology today enables us to greatly reduce the chance that a HIV-positive mother will pass HIV to her newborn if she receives proper treatment prior to delivery," said Senate Labor and Human Resources Committee Chairman Nancy Landon Kassebaum (R-Kan.). "This is why I felt it was critical to focus our federal resources on voluntary testing of mothers rather than testing newborns when it would be too late to try to prevent most HIV transmission."

Many doctors already urge testing for pregnant women, especially if they are deemed at risk for infection, and drugs can be prescribed to reduce the risk that these women will pass the AIDS virus on to their children.

The House-Senate agreement, which is subject to final approval by both houses, provides $10 million a year to assist states in implementing guidelines from the Centers for Disease Control for voluntary HIV testing, counseling and treatment of pregnant women.

Toward the end of 1998, the secretary of Health and Human Services is to determine whether mandatory testing of newborns has become standard medical practice. If it has become common practice, states would have to show by 2000 that they have reduced by 50 percent the number of newborns who develop AIDS as a result of parental infection or that 95 percent of pregnant women who at least two prenatal visits are seeking to be tested.

If states do not meet at least one of these tests, they would have to require tests for all newborns whose mothers have not undergone prenatal HIV testing or face loss of their federal AIDS funding under the Ryan White legislation.

House overwhelmingly passed the compromise measure last night. Kassebaum said the Senate will act on it shortly. President Clinton supported reauthorization of the program.

THE WASHINGTON POST
THURSDAY, MAY 2, 1996

Parties Split on Proposed Medical Savings Accounts

Republicans Push for Tax Breaks; Democrats Decry Them as Gimmicks for the Wealthy

By Clay Chandler and Spencer Rich
Washington Post Staff Writers

Mary Durbin hails her medical savings account as a godsend. Durbin, a 57-year-old audiovisual coordinator from Danville, Ohio, says the account helped cover bimonthly chemotherapy sessions and other medications at a cost to her of only $500 a year.

Durbin's medical savings account is linked to a high-deductible health insurance policy. She must pay the first $2,000 of her annual medical expenses herself, higher than in most traditional plans. But to help her meet her out-of-pocket costs, Durbin's employer, the local school system, sets aside $1,500 each year in a medical savings account. As a result, her actual liability is only $500.

Before enrolling in this type of health plan, Durbin said she spent much more of her own money on health care because of the various deductibles and copayments required by her traditional health insurance policy.

Medical savings accounts are emerging as a defining issue as politicians from both parties scramble to position themselves on economic policy issues for the fall election. Approved by the House, the accounts threaten to torpedo a consensus health insurance reform bill sponsored by Sens. Nancy L. Kassebaum (R-Kan.) and Edward M. Kennedy (D-Mass.) designed to protect workers from losing their health insurance when they change or lose their jobs.

Republicans, who are pushing for tax breaks that would encourage more Americans to open such accounts, see medical savings accounts as a perfect fit with their message of smaller government, lower taxes and greater individual responsibility and choice.

Medical savings accounts "empower people with the money they need to make their own health care decisions," said House Ways and Means Committee Chairman Bill Archer (R-Tex.), one of the idea's most staunch backers.

But Democrats have decried medical savings accounts as a tax gimmick for the rich that threatens to destroy the viability of the nation's private insurance system by sucking healthy patients out of the traditional community insurance pools. That would jack up premiums for the poor and infirm who are left behind. "They are a multibillion-dollar tax break for the wealthy and healthy, and a multibillion-dollar premium penalty for those who need insurance most," Kennedy said.

How would the GOP proposal work?

Say an employer decides it can spend $4,000 a year to provide each worker's health insurance. Under the House-approved proposal, the employer could opt to use $2,000 of that amount to buy each employee a high-deductible health plan that would cover all or most health costs above a specified deductible—not lower than $1,500 for individuals and $3,000 for families.

If the employer chose a plan with a deductible of $5,000 a year, the employee would be required to pay the first $5,000 of health expenses before the policy kicks in. The employer could place the remaining $2,000 of what it is willing to spend on each worker's health insurance in a medical savings account, deducting that contribution from its taxes as a business expense. The employee would be free to draw this money out to pay medical bills and would not be required to count the money as taxable income.

Healthy people and prudent buyers of health care may be able to hold their annual medical bills to perhaps $1,000. In that case, the employee can keep the remaining $1,000 in the account for future use on health-related expenses. After retirement, any money and interest accumulated could be withdrawn without penalty for living expenses. The remaining money also could be bequeathed to heirs without being subject to estate taxes.

Sick people or imprudent buyers of health care, however, could exceed the $2,000 an employer has put into the account. In that case, the employee must pay all expenses until hitting the $5,000 threshold.

Critics warn there is nothing in the House proposal that would require employers to put any money aside in their workers' medical savings accounts. Moreover, there is no requirement that high-deductible policies be required to cover all expenses over the deductible. Critics also worry that the lure of saving money will entice many people to scrimp on preventive health care.

House Panel Votes to Prohibit Sale of Adult Material on Bases

Associated Press

The debate focused on the First Amendment. And the merits of publications ranging from Hustler to lingerie catalogues. And which lawmakers might like a peek. Then the House National Security Committee voted yesterday to ban sale of adult magazines and videos on military bases.

Democratic critics said the proposal violates the First Amendment to the Constitution. They warned its loose wording could extend the ban to the Internet, cable television, sex manuals for married couples or the Sports Illustrated swimsuit issue.

Republican proponents insisted the measure is limited to sale or rental of sexually explicit magazines and videos. They said service people still can buy the material off base, but it should not be sold along with other goods in post exchanges.

"When it comes to First Amendment rights, there is a different standard for the military," said Rep. John M. McHugh (R-N.Y.). "Just because you have a right to read it does not mean I have an obligation to sell it to you."

The committee approved the measure by voice vote as part of the 1997 defense budget, which must be considered by the full House. "Take any one of the pictures, put it up in your work area . . . and that is a prima facie case of sexual harassment," said Rep. Robert K. Dornan (R-Calif.), a bill sponsor.

THE WASHINGTON POST
THURSDAY, MAY 2, 1996

cc: JENNIFER KLEIN

THE PRESIDENT HAS SEEN 5/30

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

May 26, 1995

MEMORANDUM FOR THE PRESIDENT AND THE FIRST LADY

FROM: Donna E. Shalala

Patricia S. Fleming, National AIDS Policy Director

SUBJECT: HIV TESTING OF PREGNANT WOMEN AND NEWBORN INFANTS

Background

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

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

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

I ACTG 076 Results

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

II Testing and Treatment of Pregnant Women

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

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

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

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

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

IV CDC Survey of HIV in Childbearing Women

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

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

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

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

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

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

V The Ackerman Bill

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

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

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

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

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

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

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

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

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

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

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

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

VII Additional Actions

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

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

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

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

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VIII Conclusion

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

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Questions and Answers

Question
For what are babies routinely tested?

Answer
No Federal laws have been enacted mandating tests of infants. Such laws vary state by state, but according to the International Society of Neonatal Screening, the most common tests are for PKU, congenital hypothyroidism, galactosemia, maple syrup urine disease, homocystinuria, biotinidase deficiency, sickle cell, syphilis, toxoplasmosis, congenital adrenal hyperplasia, cystic fibrosis, and tyrosinemia. These are congenital conditions or defects that are either curable or treatable. In addition, the test truly measures the infant's health status, not just the mother's.

Question
Are there other blinded surveys done for HIV? What about other diseases?

Answer
CDC, in collaboration with state and local health departments, other Federal agencies, blood collection agencies, and medical research institutions conducts seroprevalence studies of HIV in several subgroups of the U.S. population in order to track the epidemic and target research, prevention, and services. Anonymous, unlinked testing has been accepted as a standard for monitoring the HIV epidemic by the World Health Organization.

Question
Are there other ways to obtain the information now obtained through the survey of childbearing women?

Answer
Not with the precision of the currently suspended survey. Other methods to monitor trends in women and children will continue and be developed.

Question
What do we do about babies born to women who refuse to have their newborns tested?

Answer
The CDC guidelines urge doctors to counsel such women to be tested and empirical data to date indicate that virtually all women agree to testing. However, there is no clear answer to what to do about women who refuse to be tested. This will be a topic of the CDC consultation.

# # #

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FACSIMILE COVER SHEET

TO: Jennifer Klein

FAX NUMBER: 456-2878

FROM: Richard Socarides

DATE: 5/24/95

PAGES INCLUDING COVER SHEET: 7

COMMENTS:

If it sucks or is fabulous, please a voicemail message on 632-1204.

Thanks,

May 24, 1995

MEMORANDUM FOR THE PRESIDENT AND THE FIRST LADY
FROM: ???????
SUBJECT: HIV TESTING OF PREGNANT WOMEN AND NEWBORN INFANTS

PURPOSE: To update you on the current debate over HIV testing of pregnant women and the CDC survey of childbearing women.

BACKGROUND: Since 1988, CDC and 45 states have conducted a "blinded" survey of childbearing women to determine the prevalence of HIV in that population. Legislation is pending in Congress to "unblind" the survey in the future and release the results to mothers.

Summary

Scientific advances in the prevention of perinatal transmission of HIV resulting from the AIDS Clinical Trial Group 076 have raised a series of public policy issues that have found their way into the news and editorial pages of several major newspapers. The central questions are:

- In light of this new science, why shouldn't the Federal government impose mandatory testing of pregnant women, and,
- Why shouldn't we "unblind" the CDC survey of childbearing women and inform mothers of the HIV status of their newborns?

Due to some misunderstandings (and some blatant mischaracterizations) of the science involved, these two issues have become intertwined, but they should be viewed separately.

The key point that has been overlooked in the news coverage and commentary is that the Public Health Service has responded aggressively to the scientific advances represented by ACTG 076 by changing its policy regarding HIV testing of pregnant women and suspending the ongoing survey of childbearing women. Much work remains to be done and a consultative process with states, affected groups, medical professionals, and ethicists has begun to deal with these issues.

~~How have things changed?~~

I Testing and Treatment of Pregnant Women

Between August 1987 and February 1995, CDC guidelines urged doctors to counsel women of childbearing age to undergo voluntary HIV testing before becoming pregnant. Women who were HIV-positive were urged not to become pregnant because of the risk of passing the virus to their newborn (approximately one-in-four babies born to HIV-positive women end up HIV-positive as well).

In February 1994, researchers funded by the NIH reported the results of AIDS Clinical Trials Group Study 076 (ACTG 076), which found that the use of AZT by an asymptomatic HIV-positive woman during pregnancy, labor, and childbirth and by the newborn for six weeks following birth can reduce the risk of perinatal HIV transmission by as much as 67% (from an average of 25% to 8%).

~~Absent a method to prevent perinatal transmission of HIV, this approach made sense and was supported by the medical, public health, and medical ethics communities. However,~~ following the completion of ACTG 076, CDC consulted with outside experts and developed a new set of guidelines. The new guidelines concentrate on pregnant women and urge physicians to counsel such women to undergo voluntary HIV testing. Pregnant women who are HIV-positive are urged to undergo treatment with AZT during pregnancy and childbirth and to treat their newborn with AZT for a period of six weeks after birth. These new guidelines have also drawn strong support from medical, public health, and ethics groups. Final guidelines are to be issued within two weeks.

Quotes or more detail?

II Testing and Treatment of Newborns

CDC has also updated its policies regarding testing and treatment of babies born to HIV-positive women. Until recently, CDC recommended that HIV-positive infants with low CD-4 counts be treated with Septra/Bactrim to prevent pneumocystis carinii pneumonia (PCP), a frequently fatal opportunistic infection for pediatric AIDS cases.

In April 1995, CDC amended those guidelines to urge doctors to treat all babies born to HIV-positive women with Septra/Bactrim during the first six to 12 weeks of life.

CDC's counseling and testing guidelines also recommend that women who are not tested before giving birth undergo voluntary testing.

III CDC Survey of HIV in Childbearing Women

From 1988 to 1995, CDC, 45 states, DC, Puerto Rico, and the Virgin Islands have conducted an epidemiological survey of childbearing women in the U.S. to determine the prevalence of HIV infection in that population. The cost of the survey is $10.5 million a year. The survey uses blood taken from newborns during "heel stick" tests for genetic conditions like PKU. In order to conform with applicable state laws and the precepts of informed consent, the results are "blinded," meaning that all identifiers are separated from the blood samples taken from babies.

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

076 or the pcp info?

However, the results of ACTG 076 dictated that this survey be reexamined in the light of the new science. On May 10, Dr. Phil Lee, Assistant Secretary for Health, asked State Health Directors to suspend testing under the Survey of Childbearing Women and to join the PHS in a consultative process on the best way to proceed on surveillance and care for pregnant women in light of ACTG 076 and the guidelines on PCP prophylaxis.

IV Additional Actions

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

- NIH is funding research to continue to follow the women and infants involved in ACTG 076 to determine the long-term effects of AZT treatment during pregnancy and childbirth.
- The Agency for Health Care Policy and Research is developing materials for consumers explaining ACTG 076.
- FDA has changed its labeling instructions for AZT to allow its use in pregnant women and newborns.
- HCFA has instructed states to include perinatal use of AZT in its Medicaid drug formularies.

Koop? Brazelton?

V The Ackerman Bill

ACTG 076 has understandably spurred others to propose alternative approaches. Most prominent among those is legislation by Rep. Gary Ackerman (D-NY) to require states that participate in the CDC survey in the future to "unblind" the HIV test results and give them to the mothers. This legislation was first introduced in 1994, shortly after the release of the ACTG 076 findings, but saw no action that year. Mr. Ackerman has reintroduced the bill (H.R.1289), and now has 220 cosponsors ranging from the far right to the far left.

Mr. Ackerman's would result in mandatory HIV testing of childbearing women. Since ~~not~~ almost all infants born to HIV-positive women ~~are truly infected~~ test positive at birth, the test results tell us whether or not the woman is infected. Others, including freshman Rep. Tom Coburn (R-OK), a physician who holds the seat formerly held by Mike Synar, are suggesting mandatory testing of pregnant women and/or newborns.

The CDC survey was submitted for review by numerous ethical review boards. It would not be feasible to "unblind" this survey. In fact, the only way that CDC can ethically conduct such a survey is if the results are blinded. Otherwise, under most state laws and general principles of medical ethics, the infants' mothers would have to provide informed consent for the test to be conducted. Such an approach would skew the results and render the survey useless.

It is important to note that neither the unblinding of the CDC survey nor mandatory testing of newborns would prevent perinatal transmission of HIV since AZT must be administered during pregnancy and childbirth as well as during the first six weeks of a newborn's life. In fact, by focusing on newborns, we would be too late to save infants from HIV and AIDS.

VI Mandatory v Voluntary HIV Testing

Throughout the AIDS epidemic, public health officials have pursued a policy of routine counseling and voluntary testing for HIV. The Federal government and the states have made a small number of exceptions to that policy (military personnel, prisoners, Job Corps members). Our goal is to pull people toward testing, not to drive them away from it.

A voluntary approach is particularly important ~~as it pertains to~~ for pregnant women. The treatment course required to prevent perinatal transmission involves treatment of the woman orally during pregnancy and intravenously during childbirth and it requires the mother to administer the drug to her child three times a day for six weeks after birth. To ensure success, we need maximum cooperation from the mother. Imposition of mandatory testing would severely damage the patient-doctor relationship and the likelihood of cooperation by the mother.

examples

There is strong evidence that routine counseling and voluntary HIV testing of pregnant women works very well. In Atlanta, for example, Grady Memorial Hospital has a 96 percent success rate in getting pregnant women to volunteer for an HIV test. Similar results have been reported in Miami, Los Angeles, and New York.

Conversely, there are several examples where the use of mandatory testing has impeded treatment and prevention. They include:

- Efforts to impose mandatory drug testing on pregnant women resulted in a sharp decline in the number of women seeking prenatal care. The reason most frequently cited was women's fear that they would lose custody of their children.

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

The use of routine counseling and voluntary testing has been supported by the American Academy of Pediatrics, the American College of Obstetrics and Gynecology, the American Nurses Association, the Association of State and Territorial Health Officers, the American Public Health Association, the Pediatric AIDS Foundation, and others.

VII Conclusion

CDC's approach of routine counseling and voluntary testing of all pregnant women in the U.S. is a sound public health approach to preventing perinatal transmission of HIV. It preserves the doctor-patient relationship and engenders a cooperative relationship with HIV-positive women when it comes to treatment for their newborns. Legitimate questions have been raised about the CDC Survey of Childbearing Women. The upcoming consultation should yield sufficient information to direct future surveillance methods in the context of the latest scientific information.

Questions and Answers

Question
Has the Federal government ever mandated a specific medical test or procedure?

Answer
No, such mandates have been strictly the province of the states.

Question
For what are babies routinely tested?

Answer
It varies state by state, but according to the National Neonatal Screening Association, the most common tests are for PKU, congenital hypothyroidism, galactosemia, maple syrup urine disease, homocystinuria, biotinidase deficiency, sickle cell, toxoplasmosis, congenital adrenal hyperplasia, cystic fibrosis, and tyrosinemia.

what they are and how different from hiv?

Question
What do we do about babies born to women who have not been tested and who refuse to have their newborns tested?

Answer
The CDC guidelines urge doctors to counsel such women to be tested. There is no clear answer to what to do about women who refuse to be tested. This will be a topic of the CDC consultation.

Question
Are there other blinded surveys done for HIV? What about other diseases?

Answer
tk

Question
Are there other ways to obtain the information now obtained through the survey of childbearing women?

Answer
tk

###

DRAFT ???? HOLD CLOSE

HEALTH REFORM PROVISION IN EVERY PACKAGE OPTION

1. **Limited Insurance Reform** -- Portability plus

2. **Small Business Access to FEHBP-like Purchasing Co-Ops** (to be administered at the state level)

3. **Self-employed tax deduction to 100%** (assumed to be phased in over 3 years, but could be phased over longer period of time)

4. **Long-term care initiatives**: grants to states and private long-term care tax verifications

5. **Public health ~~service~~ investment fund**

6. **Medicare Managed Care Reform**[1]

7. **Medicaid structural and flexibility reforms**[2]

8. **Medicare Fraud and Abuse Initiative** (Operation Restore Trust)

9. **Bipartisan Commission for long-term solvency of Medicare** -- (this could include recommendations on broader health reforms and/or private sector cost containment)

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[1]Savings currently assumed in all packages from formula change in AAPCC

[2]Limited savings could be achieved through providing more flexibility to states

May 25, 1995

MEMORANDUM FOR THE PRESIDENT AND THE FIRST LADY

FROM: Donna E. Shalala
~~Carol H. Rasco~~
Patricia S. Fleming

SUBJECT: HIV TESTING OF PREGNANT WOMEN AND NEWBORN INFANTS

PURPOSE: To update you on the current debate over HIV counseling and testing of pregnant women and the CDC survey of childbearing women.

BACKGROUND: Scientific advances in the prevention of perinatal transmission of HIV have raised new public policy challenges. Among them: Should the government require pregnant women to be tested for HIV, and, should a CDC survey of childbearing women be "unblinded?" The Public Health Service has responded aggressively to the new science and promulgated new testing and treatment guidelines for pregnant women and newborns while temporarily suspending CDC's survey of childbearing women pending a review by outside experts.

Summary

Recent scientific advances in the prevention of perinatal transmission of HIV resulting from the NIH-sponsored clinical trial known as AIDS Clinical Trials Group 076 (ACTG 076) have raised a series of public policy issues that have found their way into the news and editorial pages of several major newspapers. The central questions raised by this new science are:

- Should the Federal government impose mandatory testing on pregnant women or newborns?
- Should a blinded CDC epidemiological survey of HIV in childbearing women be continued, discontinued, or "unblinded"?

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

Ackerman has suggested . . .

I ACTG 076 Results

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

II Testing and Treatment of Pregnant Women

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

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

III Testing and Treatment of Newborns

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

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

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

IV CDC Survey of HIV in Childbearing Women

From 1988 to 1995, CDC, in cooperation with state and territorial health departments in 45 states, DC, Puerto Rico, and the Virgin Islands, has conducted an epidemiological survey of childbearing women in the U.S. to determine the prevalence of HIV infection in that population. The current cost of the survey is $10.5 million a year. The survey uses leftover blood taken from approximately 45% of newborns during routine "heel stick" tests for genetic conditions. About 2.5 million babies are tested each year out of a total of 4.5 million babies born in the U.S. No additional blood is taken for this survey. To obtain the most accurate and unbiased scientific data and to conform with scientific and ethical review requirements and informed consent statutes, the results are "blinded," thus the women cannot be informed of the results. In fact, all identifiers are separated from the sample before an HIV test is run.

The CDC survey has been approved by numerous ethical review boards. It would not be feasible to "unblind" this survey. In fact, the only way that CDC can ethically conduct such a survey is if the results are blinded. Otherwise, under most state laws and general principles of medical ethics, the infants' mothers would have to provide informed consent prior to testing for the test to be conducted. Since some women would refuse testing because of their concern about a record of their infection, such an approach would skew the results and render the survey epidemiologically much less useful for monitoring the epidemic.

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

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

V ~~CDC's Consultative Process~~

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

VI The Ackerman Bill

ACTG 076 has understandably spurred a great deal of public debate. Most prominent has been around legislation by Rep. Gary Ackerman (D-NY) that would require states that conduct HIV testing of newborns to notify the mother or legal guardian of the test results. This legislation was first introduced in 1994, shortly after the release of the ACTG 076 findings, but saw no action that year. Mr. Ackerman has reintroduced the bill (H.R.1289), and now has 220 cosponsors (including 160 Democrats) ranging across the political spectrum.

If the CDC survey is continued, Mr. Ackerman's bill would amount to a policy of mandatory HIV testing of childbearing women without informed consent and would not prevent a single case of perinatal HIV transmission. Others, including freshman Rep. Tom Coburn (R-OK), a physician who holds the seat formerly held by Mike Synar, are suggesting mandatory testing of pregnant women and/or newborns.

VII Mandatory v Voluntary HIV Testing

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

A voluntary approach is particularly important ~~as it pertains to~~ for pregnant women. The treatment course ~~required to prevent~~ for perinatal transmission involves treatment of the woman ~~orally during pregnancy~~ and intravenously during childbirth, and it requires the mother to administer the drug orally to her child three times a day for six weeks after birth. To ensure success, we need maximum cooperation from the mother. Mandatory testing would severely damage the patient-doctor relationship and the likelihood of cooperation by the mother.

There is strong evidence that routine counseling and voluntary HIV testing of pregnant women can work very well. In Atlanta, for example, Grady Memorial Hospital has a 96 percent success rate in getting pregnant women to volunteer for an HIV test. Promising results have been reported at public hospitals in Miami, Los Angeles, and New York. Additionally, as the CDC guidelines become the standard of care, physicians will have a great incentive to counsel pregnant women about the benefits of testing.

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

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

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

Am Ac. of Ped.

The use of routine counseling and voluntary testing has been supported by the American College of Obstetrics and Gynecology, the American Nurses Association, the Association of State and Territorial Health Officers, the American Public Health Association, the Pediatric AIDS Foundation, and others.

VIII Additional Actions

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

- FDA has changed its labeling instructions for AZT to allow its use in pregnant women and newborns.
- HCFA has instructed states to include perinatal use of AZT in their Medicaid drug formularies.
- NIH is funding research to continue to follow the women and infants involved in ACTG 076 to determine the long-term effects of AZT treatment during pregnancy and childbirth.
- HRSA is developing an education and implementation plan for its grantees to provide services to women who need them.
- The Agency for Health Care Policy and Research is developing materials for consumers explaining perinatal transmission and AZT's role in reducing such transmission.

IX Conclusion

PHS's approach of routine counseling and voluntary testing of all pregnant women in the U.S. is a sound public health approach to preventing perinatal transmission of HIV. It preserves the doctor-patient relationship and engenders a cooperative relationship with HIV-positive women and their health care providers when it comes to treatment for themselves and their newborns. Questions have been raised about continuing the CDC Survey of Childbearing Women, and the upcoming consultation should yield sufficient information to direct future surveillance methods in the context of the latest scientific information and to direct Federal resources where they will do the most good.

comply with the full course of treatment.

It has been demonstrated to be an effective way both to get women tested and to ensure that they will

Questions and Answers

Question
For what are babies routinely tested?

Answer
No Federal laws have been enacted mandating tests of infants. Such laws vary state by state, but according to the International Society of Neonatal Screening, the most common tests are for PKU, congenital hypothyroidism, galactosemia, maple syrup urine disease, homocystinuria, biotinidase deficiency, sickle cell, toxoplasmosis, congenital adrenal hyperplasia, cystic fibrosis, and tyrosinemia. These are congenital conditions or defects that are either curable or treatable. In addition, the test truly measures the infant's health status, not just the mother's.

Question
Are there other blinded surveys done for HIV? What about other diseases?

Answer
CDC, in collaboration with state and local health departments, other Federal agencies, blood collection agencies, and medical research institutions conducts seroprevalence studies of HIV in several subgroups of the U.S. population in order to track the epidemic and target research, prevention, and services. Anonymous, unlinked testing has been accepted as a standard for monitoring the HIV epidemic by the World Health Organization.

Put in memo

Question
Are there other ways to obtain the information now obtained through the survey of childbearing women?

Answer
Not with the precision of the currently suspended survey. Other methods to monitor trends in women and children will continue and be developed.

Question
What do we do about babies born to women who refuse to have their newborns tested?

Answer
The CDC guidelines urge doctors to counsel such women to be tested and empirical data to date indicate that virtually all women agree to testing. However, there is no clear answer to what to do about women who refuse to be tested. This will be a topic of the CDC consultation.

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Why 220 cosponsors?

① Why we shouldnot/cannot unblind the CDC study?

② Why vol. v. mand. -- why vol. is the best approach

May 24, 1995

MEMORANDUM FOR THE PRESIDENT AND THE FIRST LADY
FROM: ???????
SUBJECT: HIV TESTING OF PREGNANT WOMEN AND NEWBORN INFANTS

PURPOSE: To update you on the current debate over HIV testing of pregnant women and the CDC survey of childbearing women.

BACKGROUND: Since 1988, CDC and 45 states have conducted a "blinded" survey of childbearing women to determine the prevalence of HIV in that population. Legislation is pending in Congress to "unblind" the survey and release the results to mothers.

DISCUSSION

The subject of HIV testing of pregnant women and newborn infants has been in the news quite a bit lately, including recent columns by Nat Hentoff of the Village Voice and Jim Dwyer of New York Newsday. This debate has revolved around two distinct issues: counseling and testing of pregnant women and surveillance of the HIV epidemic among childbearing women. They have, however, been intertwined in commentaries and in a political debate on Capitol Hill. It is important to view these issues separately.

I Testing of Pregnant Women

Since August 1987, the CDC has encouraged women of childbearing age to volunteer for HIV testing before becoming pregnant. Women who are HIV-positive are then urged not to become pregnant because of the risk of passing the virus to their newborn (approximately one in four babies born to HIV-positive women end up HIV-positive as well). Women who are already pregnant and do not know their antibody status have also been urged to be tested.

w/out treatment

In February 1994, researchers funded by the NIH reported the results of AIDS Clinical Trials Group Study 076 (ACTG 076), which found that the use of AZT by an asymptomatic HIV-positive woman during pregnancy, labor, and childbirth and by the newborn for six weeks following birth can reduce the risk of perinatal HIV transmission by as much as 67% (from an average of 25% to 8%).

In April 1995, CDC recommended the use of Septra/Bactrim during the first four to six weeks of life for babies born to HIV-positive women. This drug helps to prevent the onset of pneumocystis carinii pneumonia (PCP), a frequently fatal opportunistic infection for pediatric AIDS cases.

These two findings represent the most significant scientific advance in pediatric AIDS since the onset of the epidemic in 1981.

II CDC Survey of HIV in Childbearing Women

Since 1988, CDC, 45 states, DC, Puerto Rico, and the Virgin Islands have conducted an epidemiological survey of childbearing women in the U.S. to determine the prevalence of HIV infection in that population. The cost of the survey is $10.5 million a year. The survey uses blood taken from newborns during "heel stick" tests for genetic conditions like PKU. Under the ethical terms of such surveys, the results are "blinded," meaning that all identifiers are separated from the blood samples taken from babies.

More specific results ↑

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

III Changing Science Demands Changing Policies

That's what she's been saying - pub. health may need to change also

The remarkable advances represented by ACTG 076 and the PCP guidelines demand changes in policy related to both the testing of pregnant women and the CDC survey of childbearing women. Absent a treatment to prevent perinatal transmission, it was proper to maintain a stronger emphasis on testing before pregnancy. Now, it is imperative that we emphasize the importance of HIV testing as part of prenatal care. The Public Health Service has been working in a coordinated fashion to translate science into action. Those actions include:

- NIH is funding research to continue to follow the women and infants involved in ACTG 076 to determine the long-term effects of AZT treatment during pregnancy and childbirth.
- AHCPR is developing materials for consumers explaining ACTG 076.
- In August 1994, CDC issued a report recommending that all HIV-positive pregnant women be offered AZT treatment to prevent perinatal transmission.
- In February 1995, CDC issued preliminary guidelines recommending that physicians counsel all pregnant patients on the benefits of HIV testing and the potential benefits of AZT treatment if they are positive. Testing is to be voluntary and results are to be confidential. This approach has been praised by the American Academy of Pediatrics, the American College of Obstetrics and Gynecology, the American Nurses Association, the Association of State and Territorial Health Officers, the American Public Health Association, the Pediatric AIDS Foundation, and others. Final guidelines are to be issued within two weeks.

But doesn't really hit hard on mand. - v. vol why mand. wldn't be better

IV Other Approaches

ACTG 076 has understandably spurred others to propose alternative approaches. Most prominent among those is legislation by Rep. Gary Ackerman (D-NY) to require states that participate in the CDC survey to "unblind" the results and give them to the women involved. This legislation was first introduced in 1994, shortly after the release of the ACTG 076 findings, but saw no action that year. Mr. Ackerman has reintroduced the bill, H.R.1289, with 220 cosponsors ranging from the far right to the far left.

It is important to note that neither the unblinding of the CDC survey nor mandatory testing of newborns would prevent perinatal transmission of HIV since AZT must be administered during pregnancy and childbirth as well as during the first six weeks of a newborn's life. However, knowledge of a baby's HIV-status would allow for PCP prophylaxis.

Mr. Ackerman and some of his supporters have chosen to mischaracterize both the survey and the actions of the Administration in response to ACTG 076. CDC has been charged with "counting babies with HIV instead of caring for them." Others, including Dr. Art Ammann of the Pediatric AIDS Foundation, have said the use of a blinded survey is comparable to the Tuskegee experiment. [Note: While Dr. Ammann is a harsh critic of the CDC survey, he is very supportive of the counseling and testing guidelines.]

The fact is, that the CDC survey has been approved by numerous ethical review boards and is one of a number of blinded surveys conducted on a variety of conditions. In fact, the only way that CDC can ethically conduct such a survey is if the results are blinded. Otherwise, the infants' mothers would have to provide informed consent for the test to be conducted. Such an approach would skew the results and render the survey useless.

In light of the new scientific advances, on May 10, Dr. Phil Lee, Assistant Secretary for Health, asked State Health Directors to suspend testing under the Survey of Childbearing Women and to join the PHS in a consultative process on the best way to proceed on surveillance in light of ACTG 076 and the guidelines on PCP prophylaxis. This decision has drawn some sharp criticism from proponents of the Ackerman bill but also from supporters of the survey. It has, however, also slowed the momentum toward the Ackerman bill.

The bottom line is that Mr. Ackerman's proposal represents a veiled attempt to impose mandatory HIV testing on childbearing women. Since not all infants born to HIV-positive women are truly infected, the test results tell us more about the woman than the child. Others, including freshman Rep. Tom Coburn, a physician who holds the seat formerly held by Mike Synar, are flat out proposing mandatory testing.

Republican

V Mandatory v Voluntary HIV Testing

Throughout the AIDS epidemic, the Public Health Service has pursued a policy of routine counseling and voluntary testing of population groups. The Federal government and the states have made a small number of exceptions to that policy (military personnel, prisoners, Job Corps members). Our goal must be not to drive people away from testing but to pull them toward it.

A voluntary approach is particularly important as it pertains to pregnant women. The treatment course required to prevent perinatal transmission involves treatment of the woman orally during pregnancy and intravenously during childbirth and it requires the mother to administer the drug to her child three times a day for six weeks after birth. To ensure success, we need maximum cooperation from the mother and imposition of mandatory testing would severely damage the patient-doctor relationship and the likelihood of cooperation.

There is strong evidence that routine counseling and voluntary HIV testing of pregnant women works very well. In Atlanta, for example, Grady Memorial Hospital has a 96 percent success rate in getting pregnant women to volunteer for an HIV test. Similar results have been reported in Miami, Los Angeles, and New York, ~~as well as in France and Italy~~.

Conversely, there are several examples where the use of mandatory testing has impeded treatment and prevention. They include:

- Efforts to impose mandatory drug testing on pregnant women resulted in a sharp decline in the number of women seeking prenatal care. The reason most frequently cited was women's fear that they would lose custody of their children.

- Women who are 35 and older are routinely counseled on the benefits of voluntary testing for Down Syndrome. Such an approach has helped lower the rate of Down Syndrome births from 37 per 10,000 in 1983 to 26 per 10,000 in 1990.

- Voluntary screening for Tay Sachs disease helped reduce the incidence of that uniformly fatal disease by 85% between 1970 and 1980.

These are not arguments for or against mandatory

VI Conclusion

CDC's approach of routine counseling and voluntary testing of all pregnant women in the U.S. is a sound public health approach to preventing perinatal transmission of HIV. It preserves the doctor-patient relationship and engenders a cooperative relationship with HIV-positive women when it comes to treatment for their newborns.

Still, legitimate questions have been raised about the CDC Survey of Childbearing Women. The upcoming consultation should yield sufficient information to direct future surveillance methods in the context of the latest scientific information.

Questions and Answers

Question

Has the Federal government ever mandated a specific medical test or procedure?

Answer

No, such mandates have been strictly the province of the states.

Question

For what are babies routinely tested?

Answer

PKU, congenital hypothyroidism, galactosemia, maple syrup urine disease, homocystinuria, biotinidase deficiency, sickle cell, toxoplasmosis, congenital adrenal hyperplasia, cystic fibrosis, and tyrosinemia.

Explain what these are and why they are different from HIV

OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

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FACSIMILE COVER SHEET

TO: Jennifer Klein

FAX NUMBER: 456-2878

FROM: Richard Socia

DATE: 5/25/95

PAGES INCLUDING COVER SHEET: 7

COMMENTS:

Revised version with additional material on CDC's consultation process.

- CDC
- Sec/Thurm
- ASL
- Counsel
- Avis
- Corr
- HIV/AIDS Policy
- Carol
- Patsy
- Me

May 25, 1995

MEMORANDUM FOR THE PRESIDENT AND THE FIRST LADY

FROM: ???????

SUBJECT: HIV TESTING OF PREGNANT WOMEN AND NEWBORN INFANTS

PURPOSE: To update you on the current debate over HIV testing of pregnant women and the CDC survey of childbearing women.

BACKGROUND: Scientific advances in the prevention of perinatal transmission of HIV have raised new public policy challenges. Among them: should the government require pregnant women to be tested for HIV and should a CDC survey of childbearing women be "unblinded." The Public Health Service has responded aggressively to the new science and promulgated new testing guidelines for pregnant women and newborns while temporarily suspending its survey of childbearing women.

Summary

Recent scientific advances in the prevention of perinatal transmission of HIV resulting from the NIH-sponsored AIDS Clinical Trial Group 076 have raised a series of public policy issues that have found their way into the news and editorial pages of several major newspapers. The central questions are:

- In light of this new science, should the Federal government impose mandatory testing of pregnant women?
- Should the CDC survey of childbearing women be "unblinded" so that the mothers of newborns know their HIV status?

Due to some misunderstandings (and some blatant mischaracterizations) of the science involved, these two issues have become intertwined, but they should be viewed separately.

In the last 15 months, the Public Health Service has responded aggressively to the scientific advances represented by ACTG 076 by changing its policies regarding HIV testing of pregnant women and newborn infants and by suspending the ongoing survey of childbearing women. Other changes are underway, but much work remains to be done. CDC will shortly begin a consultative process with states, affected groups, medical professionals, and ethicists to deal with these issues.

I ~~ACTG 076 Results~~

In February 1994, researchers funded by the NIH reported the results of AIDS Clinical Trials Group Study 076 (ACTG 076), which found that the use of AZT by an asymptomatic HIV-positive woman during pregnancy, labor, and childbirth and by the newborn for six weeks following birth can reduce the risk of perinatal HIV transmission by as much as 67% (from an average of 25% to 8%).

II Testing and Treatment of Pregnant Women

From August 1987, to February 1995, CDC guidelines urged doctors to counsel women of childbearing age to undergo voluntary HIV testing before becoming pregnant. Perinatal transmission of HIV was identified as one of four main sources of HIV infection along with sexual activity, shared needles and works, and contaminated blood products. Women who tested HIV-positive were urged not to become pregnant because of the risk of passing the virus to their newborn. While not all children born to HIV-positive women end up HIV-positive themselves, approximately one-in-four do.

Absent a method to prevent perinatal transmission of HIV, the previous CDC policy made sense and was broadly supported by the medical, public health, and medical ethics communities. However, following the release of ACTG 076, CDC consulted with outside experts and developed a new set of guidelines. The new guidelines concentrate on pregnant women and urge physicians to counsel such women to undergo voluntary HIV testing. Pregnant women who are HIV-positive are urged to undergo treatment with AZT during pregnancy and childbirth and to treat their newborn with AZT for a period of six weeks after birth. These new guidelines have also drawn strong support from medical, public health, and ethics groups. Final guidelines are to be issued by CDC within two weeks.

III Testing and Treatment of Newborns

CDC's counseling and testing guidelines also recommend that women who are not tested before giving birth undergo voluntary testing. CDC has also updated its policies regarding testing and treatment of babies born to HIV-positive women. Until recently, CDC recommended that only HIV-positive infants with suppressed immune systems be treated with Septra/Bactrim to prevent pneumocystis carinii pneumonia (PCP), a frequently fatal opportunistic infection for babies with AIDS. In April 1995, CDC amended those guidelines to urge doctors to treat all babies born to HIV-positive women with Septra/Bactrim during the first six to 12 weeks of life.

IV CDC Survey of HIV in Childbearing Women

From 1988 to 1995, CDC, 45 states, DC, Puerto Rico, and the Virgin Islands have conducted an epidemiological survey of childbearing women in the U.S. to determine the prevalence of HIV infection in that population. The cost of the survey is $10.5 million a year. The survey uses blood taken from newborns during routine "heel stick" tests for genetic conditions. In order to conform with applicable state laws and the precepts of informed consent, the results are "blinded," meaning that all identifiers are separated from the blood samples taken from babies.

The CDC survey was submitted for review by numerous ethical review boards. It would not be feasible to "unblind" this survey. In fact, the only way that CDC can ethically conduct such a survey is if the results are blinded. Otherwise, under most state laws and general principles of medical ethics, the infants' mothers would have to provide informed consent for the test to be conducted. Such an approach would skew the results and render the survey useless.

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

However, the results of ACTG 076 dictated that this survey be reexamined in the light of the new science. On May 10, Dr. Phil Lee, Assistant Secretary for Health, asked State Health Directors to suspend testing under the Survey of Childbearing Women and to join the PHS in a consultative process on the best way to proceed on surveillance and care for HIV-positive pregnant women in light of ACTG 076 and the guidelines on PCP prophylaxis.

V CDC's Consultative Process

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

VI Additional Actions

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

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

- The Agency for Health Care Policy and Research is developing materials for consumers explaining ACTG 076.

- FDA has changed its labeling instructions for AZT to allow its use in pregnant women and newborns.

- HCFA has instructed states to include perinatal use of AZT in its Medicaid drug formularies.

VII The Ackerman Bill

ACTG 076 has understandably spurred others to propose alternative approaches. Most prominent among those is legislation by Rep. Gary Ackerman (D-NY) to require states that participate in the CDC survey in the future to "unblind" the HIV test results and give them to the mothers. This legislation was first introduced in 1994, shortly after the release of the ACTG 076 findings, but saw no action that year. Mr. Ackerman has reintroduced the bill (H.R.1289), and now has 220 cosponsors ranging from the far right to the far left.

Mr. Ackerman's bill would amount to a policy of mandatory HIV testing of childbearing women. Again, since all babies carry their mothers' antibodies at birth, a test of a newborn simply reflects the mother's HIV-status but not necessarily the newborn's own status.

Others, including freshman Rep. Tom Coburn (R-OK), a physician who holds the seat formerly held by Mike Synar, are suggesting mandatory testing of pregnant women and/or newborns.

It is important to note that neither the unblinding of the CDC survey nor mandatory testing of newborns would prevent perinatal transmission of HIV since AZT must be administered during pregnancy and childbirth as well as during the first six weeks of a newborn's life. In fact, focusing on newborns would be too little, too late to save infants from HIV and AIDS.

VIII Mandatory v Voluntary HIV Testing

Throughout the AIDS epidemic, public health officials have pursued a policy of routine counseling and voluntary testing for HIV. The Federal government and the states have made a small number of exceptions to that policy (military personnel, prisoners, Job Corps members). Our goal is to pull people toward testing, not to drive them away from it.

A voluntary approach is particularly important as it pertains to pregnant women. The treatment course required to prevent perinatal transmission involves treatment of the woman orally during pregnancy and intravenously during childbirth and it requires the mother to administer the drug orally to her child three times a day for six weeks after birth. To ensure success, we need maximum cooperation from the mother. Mandatory testing would severely damage the patient-doctor relationship and the likelihood of cooperation by the mother.

There is strong evidence that routine counseling and voluntary HIV testing of pregnant women works very well. In Atlanta, for example, Grady Memorial Hospital has a 96 percent success rate in getting pregnant women to volunteer for an HIV test. Similar results have been reported in Miami, Los Angeles, and New York.

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

- Efforts to impose mandatory drug testing on pregnant women resulted in a sharp decline in the number of women seeking prenatal care. The reason most frequently cited was women's fear that they would lose custody of their children.

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

The use of routine counseling and voluntary testing has been supported by the American Academy of Pediatrics, the American College of Obstetrics and Gynecology, the American Nurses Association, the Association of State and Territorial Health Officers, the American Public Health Association, the Pediatric AIDS Foundation, and others.

IX Conclusion

CDC's approach of routine counseling and voluntary testing of all pregnant women in the U.S. is a sound public health approach to preventing perinatal transmission of HIV. It preserves the doctor-patient relationship and engenders a cooperative relationship with HIV-positive women when it comes to treatment for their newborns. Legitimate questions have been raised about the CDC Survey of Childbearing Women. The upcoming consultation should yield sufficient information to direct future surveillance methods in the context of the latest scientific information.

Questions and Answers

Question
Has the Federal government ever mandated a specific medical test or procedure?

Answer
No, such mandates have been strictly the province of the states.

Question
For what are babies routinely tested?

Answer
It varies state by state, but according to the National Neonatal Screening Association, the most common tests are for PKU, congenital hypothyroidism, galactosemia, maple syrup urine disease, homocystinuria, biotinidase deficiency, sickle cell, toxoplasmosis, congenital adrenal hyperplasia, cystic fibrosis, and tyrosinemia.

[what they are and how different from hiv?]

Question
What do we do about babies born to women who have not been tested and who refuse to have their newborns tested?

Answer
The CDC guidelines urge doctors to counsel such women to be tested, but there is no clear answer to what to do about women who refuse to be tested. This will be a topic of the CDC consultation.

Question
Are there other blinded surveys done for HIV? What about other diseases?

Answer
tk

Question
Are there other ways to obtain the information now obtained through the survey of childbearing women?

Answer
tk

# # #

1. Background
   3. Ackerman bill
   2. Scientific advances
   1. CDC study

   OTA
   - what it was
   - what has been done in response

   CDC
   - what it was
   - Ackerman bill

2. CDC Study
   1. Can't be unblinded
   2. Would need to be redesigned
   3. CDC Consult. Process

3. Mand v. vol. early in birth
   1. Vol works
   2. mand doesn't
   3. start vol. ~~off~~ set of interv. w/ mand. intervention doesn't make sense -- need coop.

DEPARTMENT OF HEALTH & HU AN SERVICES

Chief of Staff

Washington, D.C. 20201

J. Klein - fyi

MAY 22 1995

To: Kitty Higgins
Secretary to the Cabinet

From: Kevin Thurm

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

Background

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

1) Newborn Screening Survey

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

2) Counseling and Testing Guidelines

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

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

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

The Ackerman Critique

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

Action by HHS

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

KEY ISSUES

1. Ethical Concerns with Survey:

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

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

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

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

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

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

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

Strategy

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

Attachments

CDC CENTERS FOR DISEASE CONTROL AND PREVENTION

HIV/AIDS PREVENTION

Background information on...

The HIV Survey in Childbearing Women

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

How are the findings used?

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

What are the findings?

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

What does an HIV-positive test result mean?

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

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

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

Would unblinding the survey prevent infants from being infected?

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

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

Where is the survey conducted?

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

How are the data collected?

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

How is HIV antibody testing performed?

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

How are the data from the survey reported?

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

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

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

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

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

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

MAY 11 1995

Sent to All State Health Officers

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

Dear Dr. Miike:

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

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

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

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

Sincerely,

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

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

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

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

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

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

interventions and the opportunity to provide referrals to social, legal and psychological services. It also provides and opportunity for personal risk assessment, and education about HIV.

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

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

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

Cons

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

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

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

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

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

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

[illegible] anonymously for the AIDS virus. The which thwarted legislation to open the results to mothers, was by top Administration officials in Washington despite [illegible] at the Centers for Disease Control and Prevention in Atlanta and it even surprised those who support it.

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

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

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

"We thought there was a serious question about collecting information about which we didn't inform parents," said Ms. Shalala. There would seem to be a simple solution: inform the parents, as Repre- [illegible] syphilis to sickle cell anemia.

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

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

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

people with AIDS, gay groups, [illegible] and [illegible] and abortion rights proponents. They contend mandatory testing programs would violate a woman's right to confidentiality, would discourage [illegible] seeking medical care. Most instead favor mandatory counseling for pregnant women, aimed at persuading them to take a voluntary AIDS test. "This population is so frightened you may scare people away," said Ms. Shalala.

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

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

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

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