



State of New York  
**Department of Health**  
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 Albany, New York 12237

ANTONIA C. NOVELLO, M.D., M.P.H., Dr. P.H.  
**Commissioner**

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April 24, 2006

Hon. Tom A. Coburn, M.D.  
 United States Senator  
 172 Russell Senate Office Building  
 Washington, D.C. 20510

Dear Senator Coburn:

Thank you for your March 23, 2006 letter requesting information on New York's experience in preventing mother-to-child HIV transmission (MTCT). The information presented below and the enclosed charts demonstrate New York's dramatic success in reducing both the transmission rate and the number of infected children born each year.

*Question: Could you provide a brief overview of the New York law?*

New York's comprehensive newborn HIV testing program was established by a 1996 statute amending New York's Public Health Law. The program was implemented February 1, 1997. New York State Department of Health regulations were enacted to provide the details of the program as well as to continue earlier regulations requiring clinicians practicing in regulated prenatal care settings to provide HIV counseling with testing presented as a clinical recommendation. Since the Department does not have the authority to regulate physicians in private practice, we worked with New York's professional medical organizations, including the American College of Obstetricians and Gynecologists, to establish HIV counseling with testing recommended as a standard of prenatal care regardless of setting.

The comprehensive prenatal and newborn program continued to evolve as studies on MTCT showed the benefit of abbreviated antiretroviral regimens begun in obstetrical settings and as advances in testing technology made rapid/expedited testing in obstetrical settings feasible. In 1999, the Department amended the newborn testing regulations to require expedited testing in obstetrical settings in cases where a pregnant woman presents for delivery with unknown or undocumented HIV status. In 2003, the regulations were again amended to require a 12-hour turnaround time for expedited test results, instead of the initial 48 hours allowed with the 1999 regulations. (See the enclosed graphic for an overview of current New York regulations governing prenatal and newborn HIV testing.)

The regulations for expedited testing in delivery settings prompted birth facilities to educate attending physicians and prenatal clinics to increase their prenatal testing rates. As a result, the vast majority of HIV-positive women are known prior to admission for delivery, with a small number identified through expedited testing in the obstetrical setting. Newborn HIV screening has become the "safety net." For example, acute HIV infection during pregnancy following a documented negative prenatal HIV test has been identified in a few cases by the infant's positive newborn screen.

Birth facilities are required to report data on maternal prenatal and expedited HIV testing to the Newborn Screening Program. The Department uses this data to monitor program implementation. In addition, all birth facilities in New York receive facility-specific performance data on a routine basis for internal quality improvement activities.

*Question: Would you deem the New York law a success?*

New York's newborn testing law is part of a comprehensive program for reducing MTCT, which includes the following goals:

- Ensuring access to prenatal care for all pregnant women;
- Establishing HIV counseling and recommended testing as a standard of prenatal care;
- Ensuring that all HIV-positive pregnant women are offered antiretroviral therapy (ART) for their own health and to reduce the risk of MTCT;
- Ensuring that HIV test information is transferred from the prenatal care site to the anticipated birth facility;
- Requiring expedited testing in the delivery setting for all women/newborns for whom prenatal HIV test results are not available; and
- Conducting HIV testing as a quality check on all newborn blood specimens submitted to the Department's Newborn Screening Program.

To reach these goals, the Department conducts surveillance; closely monitors compliance with regulations; sponsors enhanced outreach to high risk pregnant women not in prenatal care; provides consultation and technical assistance to hospital obstetrical departments; conducts quality reviews; and supports clinicians through education, training and the dissemination of state-of-the-art clinical practice guidelines.

The comprehensive program has had dramatic success. New York has the largest number of births to HIV-positive women in the United States, experiencing a high of 1,898 HIV-positive birth events in 1990. At that time, the mother-to-child transmission rate was estimated to be 25 to 30 percent, representing

approximately 475 to 570 HIV-infected infants born in New York in 1990. In the first year (1997) of routine newborn screening, there were 941 positive birth events with 97 (10.9 percent) infected infants. In 2004, there were 624 positive birth events and 16 (2.8 percent) infected infants. (See Charts 1 and 2 for additional data.)

*Question: Has there been any evidence that this law has discouraged women from seeking prenatal care?*

There is no evidence that pregnant women have been discouraged from seeking prenatal care or were going out-of-state to deliver following implementation of the comprehensive program. (See Chart 3.) The rate of acceptance of HIV testing among women in prenatal care increased and rates of no prenatal care in both HIV-positive and HIV-negative women in New York decreased.

*Question: What was the percentage of pregnant women who received HIV testing prior to enactment of the law compared to the percentage receiving testing now?*

Statewide data on HIV testing of pregnant women prior to the implementation of the comprehensive program is not available. In 1997, when New York's comprehensive newborn program began, 64 percent of all pregnant women were aware of their HIV status on admission for delivery. In 2004, 95 percent of all women presenting delivery knew their HIV status. (See Chart 4.)

*Question: What percentage of pregnant women refuse HIV testing? What are their reasons for refusing testing?*

In 2004, 5 percent of women presenting for delivery did not have documentation of a prenatal HIV test. We suspect this represents women without prenatal care rather than women declining prenatal testing. A key factor in a woman's acceptance of prenatal HIV testing is the recommendation by her prenatal clinician that it is in the woman's and her infant's best interests to know her HIV status.

*Question: What percentage of newborns and new mothers are sent home after delivery with an unknown HIV status? How does this compare to the percentage prior to the enactment of the law?*

This information is not available prior to February 1, 1997. In 2004, less than 0.4 percent of the almost 240,000 infants born in New York State lacked documentation submitted to the Department on either prenatal testing or expedited testing in the obstetrical setting.

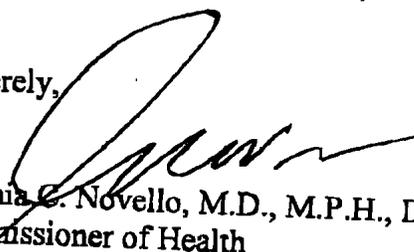
*Question: What percentage of women and children that test positive for HIV antibodies are then referred into appropriate care?*

Regulations require that birth facilities ensure that exposed newborns have diagnostic testing (such as DNA PCR testing) and that birth facilities submit the result of the first diagnostic test to the Department. The Department uses this as an indicator that exposed newborns are in care. To facilitate diagnostic testing of HIV-exposed infants, the Department has had a free diagnostic testing service for HIV-exposed infants since 1995.

An indicator, such as diagnostic testing of newborns, is not readily available to ensure HIV-positive pregnant/delivering women are in care. To address this, the Department is implementing an initiative to link HIV-positive pregnant women/delivering women to intensive case management, particularly those who have difficulty remaining in prenatal care or who deliver without prenatal care. In addition, all HIV-positive births are considered sentinel events. The AIDS Institute's review agent conducts medical record reviews on the prenatal, obstetrical, newborn and pediatric records associated with these events. Chart 5 provides trend data on antiretroviral regimens obtained from chart review for HIV-positive birth events from 1997 through 2002. This data is being updated to include 2003 and 2004.

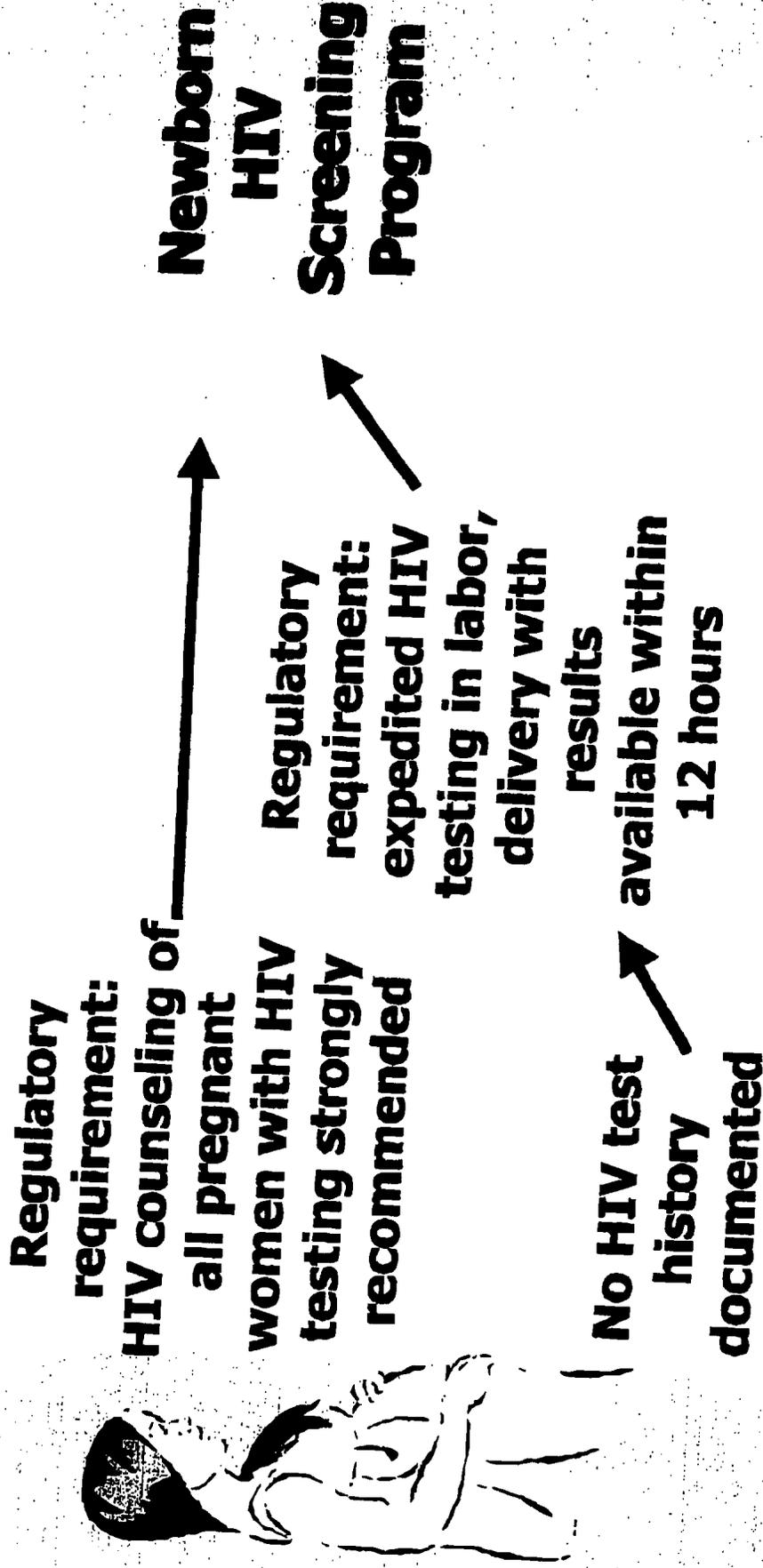
Thank you for your inquiry regarding New York's experience in reducing mother-to-child HIV transmission. If you would like additional information, please contact Dr. Guthrie Birkhead, Director of the AIDS Institute, at (518) 472-5382, or by email at [gsb02@health.state.ny.us](mailto:gsb02@health.state.ny.us).

Sincerely,

  
Antonia C. Novello, M.D., M.P.H., Dr.P.H.  
Commissioner of Health

Enclosures  
cc: Dr. Birkhead

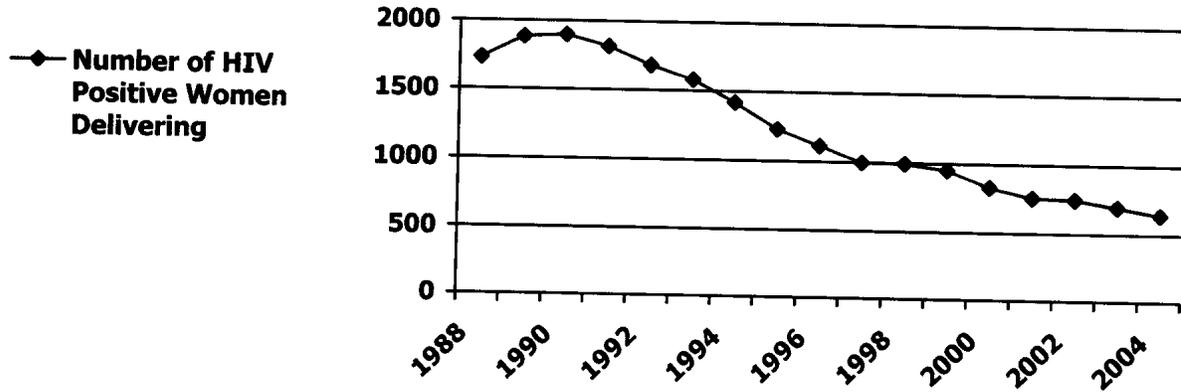
# HIV Counseling and Testing of Pregnant Women and Newborns in New York State



**Mother: Consent required**  
**Newborn: No consent required**

**Chart # 1**

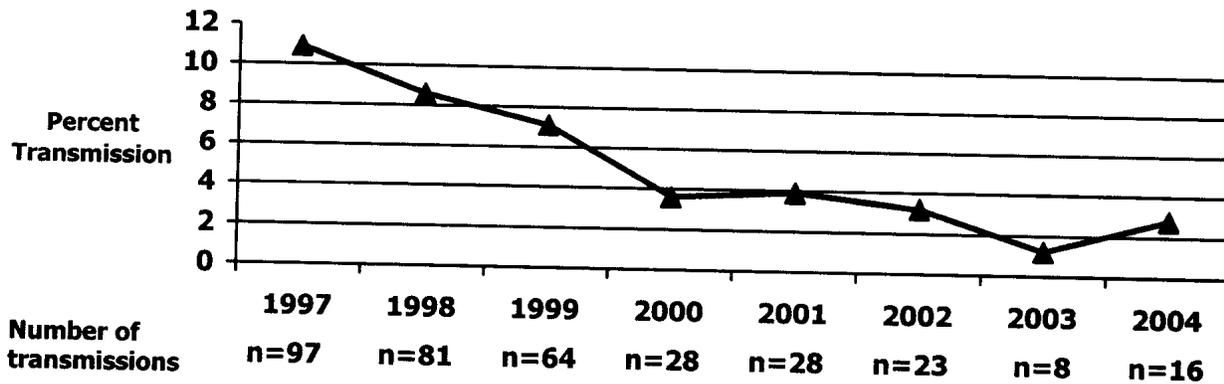
**NYS Survey of Childbearing Women  
HIV Prevalence By Year of Delivery: 1988-2004**



Since 1990, there has been a 66% decline in the number of HIV-infected women giving birth in NYS: 1,898 in 1990 to 642 in 2004

**Chart # 2**

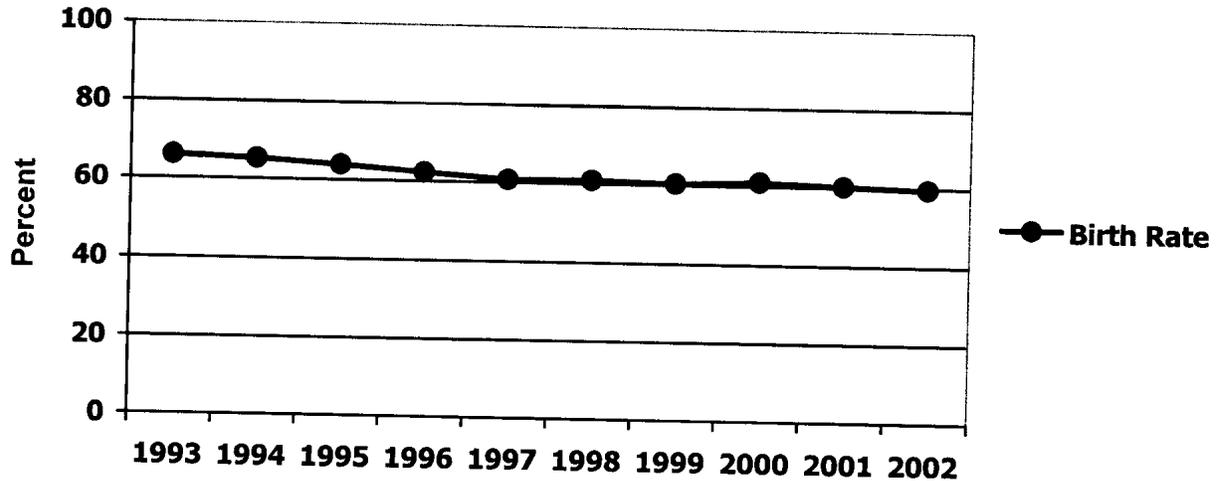
**Mother-to-Child Transmission Rate  
New York State, 1997-2004**



Percent of deliveries by HIV positive mothers that resulted in HIV transmission to the baby

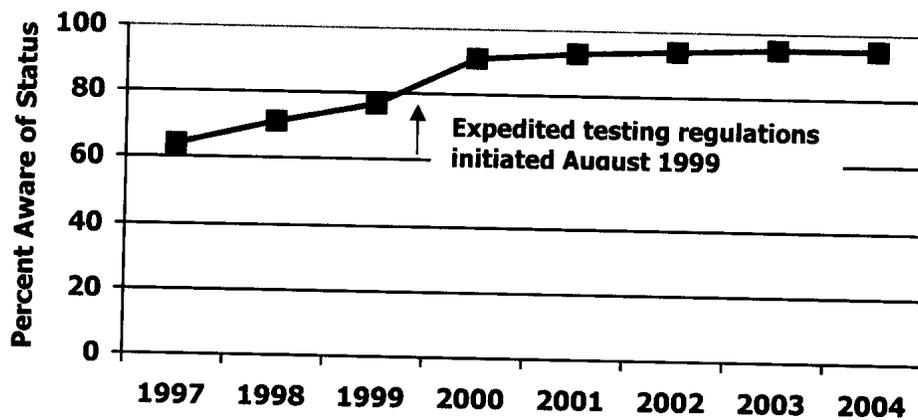
**Chart # 3**

**New York State Birth Rate Per 1,000 Females Age 15-44  
1993-2002**



**Chart # 4**

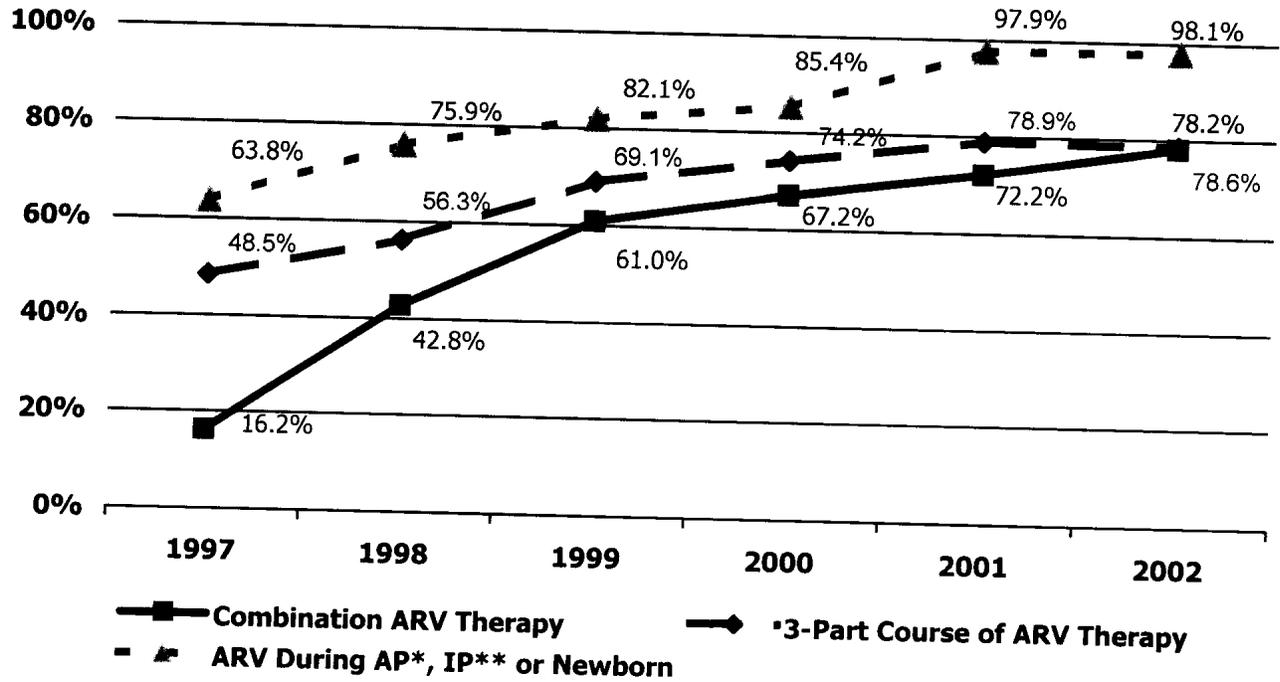
**Women in NYS Aware  
of HIV Status Before Delivery**



**From 1997 to 2004, the percentage of women aware of their HIV status before delivery increased from 64% to 95%.**

**Chart # 5**

**Trends in Health Care for HIV-Infected Women in NYS:  
Antiretroviral Therapy (ARV) and Elective C-Section, 1997-2002**



\*AP = Antepartum (prenatal) period      \*\*IP = Intrapartum (During labor and delivery)