

**Prevention of Perinatal HIV
Transmission:
Expedited HIV Testing
for Pregnant Women
in the Labor, Delivery & Neonatal
Setting**

**New York State
Department of Health
AIDS Institute**

Chronology of Prenatal and Newborn HIV Testing in NY

- **Nov 1987: Survey of Childbearing Women**
 - Blinded testing of all newborns.
- **May 1996 - Jan 1997. Regulations:**
 - Required prenatal counseling with recommended testing in regulated settings.
 - Consented newborn testing.
- **Feb 1997. State Law:**
 - Comprehensive Newborn HIV Testing Program.
- **August 1999-Revised Regulation:**
 - Expedited HIV testing program.

Universal Prenatal HIV C&T New York State, 1998

- 250,834 women delivered
- 54.5 % tested during current pregnancy
- 16.6 % tested prior to pregnancy
- 23.6% no prior testing
- 5.3% unknown testing history

Problem Statement

- 45.5 % of women had no documented HIV test result from their current pregnancy
- Up to 520 HIV+ women may not have known their HIV status
- Missed opportunity for prophylaxis to reduce HIV transmission

When Does Perinatal HIV Transmission Occur?

- Antepartum: approx. one third
- Intrapartum: approx. two thirds
- Breastfeeding: 14% additive risk

Abbreviated Perinatal Regimens

- Thailand: ZDV from 36 weeks and during labor. *Transmission 9.4% ZDV group vs 18.9% placebo¹*
- UNAIDS PETRA: ZDV and 3TC intrapartum and 1 week postpartum (mother and baby).
Transmission 10.8% ZDV/3TC vs 17.2% placebo²
- HIVNET 012: ZDV or Nevirapine intrapartum and for newborn. *Transmission 13.1% NVP, 25.1% ZDV³*
- NYS observational: ZDV intrapartum/newborn or newborn only. *Transmission 10% intrapartum, 9.3% newborn only, 26.6% no ZDV⁴*

¹ Shaffer et al. Lancet 1999; 353:773, ² Saba et al. 6th conf. Retroand Oppor Inf 1999, ³Guay et al. Lancet 1999;354:795, ⁴ Wade et al. NEJM 1998;339:1409

Reasons for No HIV Test Results at Labor/Delivery

- No prenatal care
- Prenatal care without HIV counseling
- HIV counseled and not tested
- Test result not transferred to delivery medical record

Current Program

- Prenatal HIV counseling, and testing recommended
- Routine screening of all infants under the Newborn Screening Program (NSP)
- Test results from NSP available in 1-2 weeks
- Strong linkages to care once identified
- Expedited HIV testing required intrapartum (consented) or of newborn (without consent) if HIV test results not available from the current pregnancy and mother not known HIV positive

Expedited Testing: Rationale

- Promotes access to intrapartum or newborn ZDV prophylaxis
- If mother is unable or declines prenatal or intrapartum ZDV, newborn may still benefit from prophylaxis
- Promotes early identification of infected infants, allowing combination therapy

Expedited HIV Testing Regulations: New York State

- Apply only when mother's HIV status is unknown at delivery
- Require hospital to provide immediate HIV testing
 - mother (with consent) during labor and delivery
 - or, newborn (without consent) immediately after birth

Expedited HIV Testing Regulations: New York State

- Require results to be available as soon as possible, not later than 48 hours
- Similar to hepatitis B surface antigen testing requirement
- Allow reporting of preliminary HIV test results when requested by a physician

Facility Responsibilities

- Review prenatal record when received and at admission
- Provide HIV counseling for women in labor who have no documented HIV test result from this pregnancy

Facility Responsibilities

- Must provide immediate testing
 - mother (with consent)
 - newborn (without consent)
- Capacity to report preliminary HIV test result
- Offer ZDV prophylaxis when appropriate

Interpretation of Positive Preliminary HIV Test Result

- Discuss likelihood of true positive
 - based on risk factors & seroprevalence
- Offer initiation of ZDV prophylaxis
- Advise against breastfeeding, pending confirmatory result

Discharge Considerations

- Availability of confirmatory test result
- Return clinic visit
- Consider delay of discharge
- ZDV prescription for infant if needed
- Specialty referrals
- Assess need for additional services

Projected Utilization of Expedited HIV Testing

- 250,000 births per year, 0.4% HIV-positive
- ~ 1000 HIV- positive women give birth each year
- 90% of **all** pregnant women are tested during pregnancy or are known HIV positive (April 2000)
- 25,000 pregnant women are eligible for expedited HIV testing; approximately 120 of these women will be HIV-positive each year

Continuation of Universal Newborn Screening Program

- All infants are still tested for HIV.
- In postpartum period, all women will be counseled about universal HIV testing in the Newborn Screening Program

**Predictive Value Positive of
HIV Tests (SUDS, EIA)
with Different HIV Prevalence**

Prevalence	PVP/SUDS	PVP/EIA
10%	96%	99%
5%	91%	98%
1%	67%	91%
0.5%	50%	83%
0.3%	38%	75%
0.1%	18%	50%

Predictive Value of Test Combinations in Low Prevalence Population (1.5%)

	Sensitivity (95% CI)	Specificity (95% CI)	PVP	PVN
Abbott EIA/Gen Sys EIA	100 (77-100)	100 (99.6-100)	100	100
Abbott EIA/HIVCHEK	100 (77-100)	100 (99.6-100)	100	100
Abbott EIA/Genie	100 (77-100)	100 (99.6-100)	100	100
Abbott EIA/Retrocell	100 (77-100)	100 (99.6-100)	100	100
Retrocell/HIVCHEK	100 (77-100)	100 (99.6-100)	100	100
Retrocell/Genie	100 (77-100)	100 (99.6-100)	100	100
HIVCHEK/Genie	100 (77-100)	100 (99.6-100)	100	100

Stetler, HC et al. AIDS 1997;11:369-375

NY Expedited HIV Testing 10/99-4/00

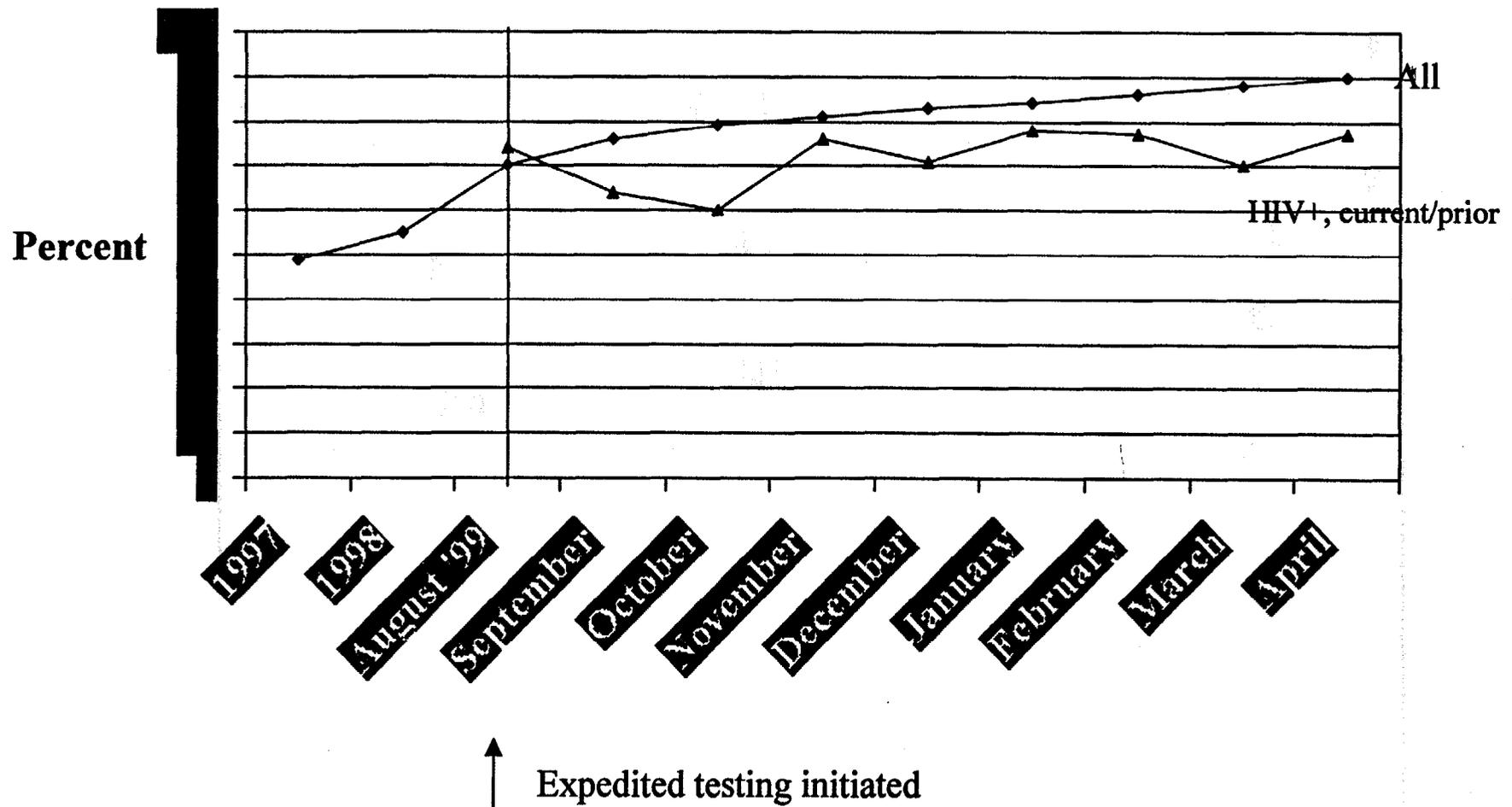
	HIV+	HIV-
	n (%)	n (%)
• Births	484	143,593
• Tested during pregnancy	285 (59)	121,316 (85)
• Tested prior to pregnancy	138 (29)	3,233 (2)
• Required expedited testing	61 (13)	19,044 (14)
– Expedited testing done	45 (74)	ND
– Missed opportunities	16 (26)	ND

Preliminary Positive Test Results: NY Expedited HIV Testing 10/00-4/00

• Positive expedited screening test	58*
– Confirmed Positive	38 (66%)
• EIA	18
• SUDS	20
– False Positive	17 (29%)
• EIA	3
• SUDS	14
– Pending	2 (3%)
– Western Blot Indeterminate	1 (2%)

*Includes 8 previously known positive

Percent of Women Tested During the Current Pregnancy



Conclusions: Expedited Testing

- Antiviral therapy during labor or soon after birth prevents ~50% of mother-to-child HIV transmission.
- 10-15% of HIV-infected pregnant women are diagnosed at labor only with the use of rapid tests.
- In New York State alone, approximately 50 HIV infections in infants each year can be prevented by expedited testing and timely antiretroviral therapy.
- Use of >1 rapid test would prevent the unnecessary treatment of 30-40% of infants whose initial rapid test is false-positive.
- Additional approved rapid tests are urgently needed.

Speaker – Nancy A. Wade, M.D., M. P. H.

Listed Reprints (No reprints provided)

1. Wade, Nancy A.; Burkhead, Guthrie S.; Warren, Barbara L., et al. Abbreviated Regimens of Zidovudine Prophylaxis and Perinatal Transmission of the Human Immunodeficiency Virus, *The New England Journal of Medicine*, November 12, 1998 Vol. 339, Number 20, pp. 1409-1414.
2. Shaffer, Nathan; Chuachoowong, Rutt; Mock, Philip A.; et al. Short-course Zidovudine for Perinatal HIV-1 Transmission in Bangkok, Thailand: A Randomised Controlled Trial, *The Lancet*, Vol. 353, pp. 774-780, March 6, 1999.
3. Guary, Laura A.; Musoke, Phillipa; Fleming, Thomas, et al. Intrapartum and Neonatal Single-Dose Nevirapine Compared With Zidovudine for Prevention of Mother-to-Child Transmission of HIV-1 in Kampala, Uganda: HIVNET 012 Randomised Trial, *Lancet* 1999; 354; 795-802.
4. Public Health Service Guideline for the Management of Health-Care Worker Exposures to HIV and Recommendations for Postexposure Prophylaxis, *MMWR*, May 15, 1998, Vol. 47, No. RR-7, CDC, Atlanta, GA.