
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% placebo*¹
- UNAIDS PETRA: ZDV and 3TC intrapartum and 1 week postpartum (mother and baby). *Transmission 10.8% ZDV/3TC vs 17.2% placebo*²
- HIVNET 012: ZDV or Nevirapine intrapartum and for newborn. *Transmission 13.1% NVP, 25.1% ZDV*³
- NYS observational: ZDV intrapartum/newborn or newborn only. *Transmission 10% intrapartum, 9.3% newborn only, 26.6% no ZDV*⁴

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

<table>
<thead>
<tr>
<th>Prevalence</th>
<th>PVP/SUDS</th>
<th>PVP/EIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>10%</td>
<td>96%</td>
<td>99%</td>
</tr>
<tr>
<td>5%</td>
<td>91%</td>
<td>98%</td>
</tr>
<tr>
<td>1%</td>
<td>67%</td>
<td>91%</td>
</tr>
<tr>
<td>0.5%</td>
<td>50%</td>
<td>83%</td>
</tr>
<tr>
<td>0.3%</td>
<td>38%</td>
<td>75%</td>
</tr>
<tr>
<td>0.1%</td>
<td>18%</td>
<td>50%</td>
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</table>
Predictive Value of Test Combinations in Low Prevalence Population (1.5%)  

<table>
<thead>
<tr>
<th>Test Combination</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
<th>PVP</th>
<th>PVN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott EIA/Gen Sys EIA</td>
<td>100 (77-100)</td>
<td>100 (99.6-100)</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Abbott EIA/HIVCHEK</td>
<td>100 (77-100)</td>
<td>100 (99.6-100)</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Abbott EIA/Genie</td>
<td>100 (77-100)</td>
<td>100 (99.6-100)</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Abbott EIA/Retrocell</td>
<td>100 (77-100)</td>
<td>100 (99.6-100)</td>
<td>100</td>
<td>100</td>
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<tr>
<td>Retrocell/HIVCHEK</td>
<td>100 (77-100)</td>
<td>100 (99.6-100)</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Retrocell/Genie</td>
<td>100 (77-100)</td>
<td>100 (99.6-100)</td>
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<tr>
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</tr>
</tbody>
</table>

Stetler, HC et al. AIDS 1997;11:369-375
NY Expedited HIV Testing 10/99-4/00

<table>
<thead>
<tr>
<th>Category</th>
<th>HIV+ n (%)</th>
<th>HIV- n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Births</td>
<td>484</td>
<td>143,593</td>
</tr>
<tr>
<td>Tested during pregnancy</td>
<td>285 (59)</td>
<td>121,316 (85)</td>
</tr>
<tr>
<td>Tested prior to pregnancy</td>
<td>138 (29)</td>
<td>3,233 (2)</td>
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<tr>
<td>Required expedited testing</td>
<td>61 (13)</td>
<td>19,044 (14)</td>
</tr>
<tr>
<td>Expediting testing done</td>
<td>45 (74)</td>
<td>ND</td>
</tr>
<tr>
<td>Missed opportunities</td>
<td>16 (26)</td>
<td>ND</td>
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</table>
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

- All
- HIV+, current/prior

Expedited testing initiated
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.

