Getting to Zero

Using Rapid Tests to Eliminate Mother-to-Child HIV Transmission
Health Research & Educational Trust
Centers for Disease Control and Prevention

Rationale for Rapid Testing in L&D, Nursery

- 1 in 5 people who are HIV infected don’t know it.
- Heterosexual women comprise a significant group of HIV-infected individuals in the US.
- In 2006, there were 9,801 AIDS cases among women in the U.S.

More Rationale

- 91% of pediatric AIDS cases from mother-to-child transmission.
- Rapid tests produce results in as few as 10 minutes.
Overview of Workshop

- HRET’s role in preventing MTCT
- Rationale for rapid testing
- HIV status, trends, demographics
- CDC guidelines, state laws
- Testing options, operational issues
- Consent

Overview, cont.

- Treatment / linkage to care
- Reporting requirements
- Partner services
- Cultural competency resources
- Perinatal resources

HRET -- Overview

- Health Research & Educational Trust – the research and education affiliate of the American Hospital Association.

- www.hret.org
HRET and the CDC

- Current collaboration with the CDC
  - HIV testing in hospitals
  - National survey of HIV testing in hospitals
  - HIV testing in EDs
    - www.edhivtestguide.org
  - Eliminating perinatal HIV transmission
  - Cost and reimbursement guide
    - www.hret.org/hiv-cost

Perinatal HIV Prevention in the US

HRET’s Role

- National survey of hospitals
- Developed tools and training materials for hospitals
- Established a panel of experts in maternal and child health
- Expanded MCH providers’ peer networking opportunities

Perinatal HIV Activities

Workshops
- Through state and metro hospital associations
- L&D, Nursery, Lab, Infectious Disease, Pharmacy

Cost/Reimbursement Tools
- Cost calculator
- Reimbursement information
- www.hret.org/hiv-cost
Perinatal HIV Activities

Learning Collaboratives

- Three - two reps from six hospitals each from 2010 to 2012
- First: Sole Community Hospitals and Rural Referral Centers
- In-person meetings and conference calls

Perinatal HIV Activities

Online Guide

- Step-by-step guide
- Prenatal, third-trimester and L&D testing
- Resources
- Dynamic, not static
- In partnership with CDC, ACOG and FXB Center

Perinatal HIV Activities

- National Stakeholders Group
  - Research/Long-Term Follow-Up
  - Case Finding
  - Surveillance/Data Reporting
  - Reproductive Health/Family Planning
  - Case Review and Community Action
  - Comprehensive Care and Social Services
How Far We’ve Come

- 1982 – NIH declines a proposed study to determine whether women contract AIDS.
- 1982 – Women with AIDS are classified under the risk category of “prostitutes.”
  
  Source: Community Education Group

How Far We’ve Come (cont.)

- 1988 – *Cosmopolitan* article
  - Women can have unprotected vaginal intercourse with an HIV-infected man if they have healthy vaginas;
  - It is impossible to transmit HIV via the missionary position.

  Source: Community Education Group

How Far We Have to Go

- 1996 – AIDS becomes the No. 1 cause of death for African-American women ages 25-44.
- 2003 – South Africa’s former health minister advocated garlic to combat HIV rather than ARVs.

  Source: African-Americans Reach and Teach Health
How Far We Have to Go (cont.)

- More than 300,000 females are living with HIV/AIDS in the U.S.

Making Progress

- Perinatally acquired HIV infections in U.S.
  - 1991: 1,650
  - 2007: 139 in 34 states and 5 dependent areas with name-based reporting

Rationale for Rapid Testing in L&D, Nursery

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- Heterosexual women are a significant HIV-infected demographic.
- In 2006, there were 9,801 AIDS cases among women in the U.S.
- 91% of pediatric AIDS cases from mother-to-child transmission.
Effectiveness

- New rapid tests provide results in as few as 10 minutes.
- These tests allow us to identify undiagnosed HIV cases in L&D and intervene to reduce transmission.
- Best case = Treating mother with ARVs during pregnancy, labor and delivery, and treating baby with ARVs beginning within 12 hours of birth. *Reduces risk of MTCT to <2%!* 

Effectiveness

- Can be effective when ARVs started during labor and given to newborn.
- Can be effective even when ARVs are given only to neonate and not to mother.

Recent Studies

- **University College London**
  - 5,151 pregnancies from 2000 to 2006
  - MTCT decreased to from 20% to 1.2% with routine screening.
- **McGill University, Montreal**
  - Clinical trial in India of 1,222 women
  - Rapid testing found 15 HIV+ moms
  - 13 babies born HIV-; two HIV+ babies did not survive
Recent Studies (cont.)

- The Elizabeth Glaser Pediatric AIDS Foundation
  - Conclusion: PMTCT is achievable and an essential part of the continuum of care.

Does This Apply to My Hospital?

- There are HIV-infected men and women in every community - urban, suburban and rural - in every socioeconomic group.
- Women of childbearing age, especially women of color, are increasingly at risk.

Does This Apply to My Hospital? (cont.)

- In 2006, AIDS case rate for Black women was 21 times the rate for white women.
  - Latinas - 5 times white women
  - Am. Ind./Alaska Native - 3.6 times white women
  - Asian/Pacific Islander - 1.6 times white women

- Majority of cases of MTCT are among Black Americans.
- Women from out of town may plan to deliver at their hospital - but end up at yours. Be prepared!
Getting Started
- Identify champions
- Include affected departments
  - Labor
  - Delivery
  - Nursery
  - Lab
  - Pharmacy
  - Infectious disease
  - Medical staff
  - Risk management

Critical Elements
- State laws
- CDC recommendations
- Hospital policies and procedures

Challenges in Hospitals: HIV Testing
- Legal restrictions (state, local, hospital policies)
- Availability of prenatal care test results
- Counseling and consent
- Patient privacy/confidentiality
- Staff resources/turnover
- Cost/reimbursement
- Confirmatory testing and patient follow-up
Challenges in Hospitals: Prophylaxis/ Treatment

- Availability of appropriate maternal and neonate medications
- Availability of medication 24/7
- Availability of outpatient medication
- Possibility of false positives, risk management
- Labeling and administering meds while maintaining patient privacy
- Appropriate medication counseling

What About Cost?

- Cost of tests is lowering and often reimbursed by insurance and, in some states, Medicaid.
- May be possible to collaborate, perhaps through state health departments, to reduce costs of testing supplies (340b programs).

What About Cost? (cont.)

- Cost of ARVs for neonate is more than offset by cost of lifetime of care if child is infected.
- 2006 study found average lifetime cost of care from diagnosis as HIV+ = $618,900 over 24 years (not perinatal)
- Health reform eliminates cost sharing for USPSTF recommendations, including HIV screening
Everybody wins!

- Rapid HIV testing in L&D and the nursery provides a last opportunity to prevent MTCT while bridging infected mothers to care and services.
Preventing Mother to Child HIV Transmission: Achieving Greater Success in the United States

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François-Xavier Bagnoud Center
School of Nursing
University of Medicine & Dentistry of New Jersey
Adapted from a slide set by:
Margaret A. Lampe, RN, MPH
Division of HIV/AIDS Prevention
National Center for HIV, Viral
Hepatitis, STD & TB Prevention
Centers for Disease Control and
Prevention

With support from the
Centers for Disease Control and Prevention

The findings and conclusions in this presentation are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.
Elimination of Perinatal HIV—Why?

- Elimination is feasible
  - We know how
  - We have the tools

- Missed opportunities account for most remaining transmissions

- Cost-savings potentially $25,000,000/yr
  - Discounted lifetime medical care cost for an HIV-infected child= $250,000
  - > 100 perinatal infections per year remaining

- It’s the right thing to do.
Estimated Numbers and Percentages* of AIDS Cases among Female Adults and Adolescents 1985–2007—United States and Dependent Areas

Note. Data have been adjusted for reporting delays.
*Percentage of all cases that were diagnosed among females.
Estimated Number of Perinatally Acquired AIDS Cases by Year of Diagnosis, 1985–2006—United States and Dependent Areas

ACTG 076 & USPHS
ZDV Recs

CDC HIV Testing Recs

~95% reduction

Note. Data have been adjusted for reporting delays and cases without risk factor information were proportionally redistributed.
HIV infected infants in the United States: model estimates from 1978-2005

Davis et al., *JAMA* 1995;274:952-5.

Taylor et al., unpublished, 2008.
Annual rate of diagnoses of perinatal HIV infection per 100,000 infants aged ≤1 year, by race/ethnicity — 34 states, 2004-2007

[Graph showing annual rate of diagnoses of perinatal HIV infection per 100,000 infants aged ≤1 year, by race/ethnicity.]

- Black/African American: p=0.003
- Hispanic/Latino: p=0.04
- White
- Other

CDC. MMWR, Feb 5, 2010, Vol. 59 No. 4
Racial/ethnic distribution in total population, infants aged ≤ 1 year, persons aged ≥13 years with diagnoses of HIV infection & children with diagnoses of perinatal HIV infection, 34 states, 2004-2007

CDC. MMWR, Feb 5, 2010, Vol. 59 No. 4
Perinatally-acquired HIV/AIDS diagnosis by the number of diagnoses made at an institution, 2001-2005, HARS, 33 states

<table>
<thead>
<tr>
<th>Number of diagnoses per institution</th>
<th>N=353*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>&gt;= 2</td>
</tr>
<tr>
<td>135 (38.2%)</td>
<td>218 (61.8%)</td>
</tr>
</tbody>
</table>

> 1/3 of cases are diagnosed at very low prevalence institutions

*Children with available data on institution at which diagnosis was made
Number of perinatally-acquired HIV diagnoses by PMCT funding 2001-2005, HARS, 33 states

Number of diagnoses  
N=529

<table>
<thead>
<tr>
<th>Grantee State n=6</th>
<th>Non-grantee State n=23</th>
</tr>
</thead>
<tbody>
<tr>
<td>331 (62.6%)</td>
<td>198 (37.4%)</td>
</tr>
</tbody>
</table>

> 1/3 of cases are diagnosed in areas without PMCT funding
Rationale for Rapid HIV Testing for Women in Labor

- 6,000-7,000 HIV infected women gave birth in 2000

- 280-370 HIV infected infants

- 40% of infected infants born to women with unknown HIV status prior to delivery
  
  Office of Inspector General, July 2003

- In 2002, only 69% of post-partum women reported HIV testing during prenatal care

  Anderson & Sansom, MCH Journal, June 2006
Results of Pediatric AIDS Clinical Trials Group 076 - 1994

- Intervention led to a 66% reduction in risk for transmission (P= <0.001)
- Efficacy was observed in all study subgroups
Risk of Perinatal HIV Transmission and Timing of Antiretroviral (ARV) Prophylaxis

- **No ARV + BF**
  - In Labor: ~25%
  - No ARV: 40%
  - Pregnancy: <2%

References:
- Wade, et al. 1998 NEJM 339;1409-14
- Guay, et al. 1999 Lancet 354;795-802
- Fiscus, et al. 2002 Ped Inf Dis J 21;664-668
- Moodley, et al. 2003 JID 167;725-735
The Case for Rapid HIV Testing During Labor

ZIDOVUDINE administration during pregnancy and the neonatal period reduces the rate of mother-to-child transmission of human immunodeficiency virus (HIV) type 1 by approximately two thirds. Analysis of data from the AIDS Clinical Trial Group (ACTG) 076 cohort[1] and subsequent reports[2-4] has revealed perinatal transmission rates in the 5% to 8% range in individual treated groups compared with previously reported rates of 20% or greater in untreated groups.[5] In late 1993, the Public Health Service developed recommendations for the use of zidovudine during the antepartum, intrapartum, and neonatal period,[6] establishing the national standard of care for identified HIV-infected pregnant women.

The success of ACTG 076, while impressive, is not absolute; 2 challenges remain to optimize the prevention of mother-to-child transmission of HIV. First, steps must be taken to further reduce the rate of transmission below the 5% level reported among the treated mothers in the ACTG 076 trial. Trials of multiple antiretroviral agents are now being undertaken toward that end. However, even the development of improved therapeutic and diagnostic tools will not signal the death knell of perinatal infections. The continued existence of congenital syphilis, despite the availability of a clinically effective prevention protocol, is a case in point. In New York, the de jure standard of prenatal care is for all women to be tested for syphilis during pregnancy and for all infected women to be treated. Despite these stringent preventive measures, congenital syphils rates as high as 10% have been reported from some hospitals in New York State within the last decade.[7] As with HIV, women at highest risk for delivering a child with a prenatal case than if transmission rates were reduced from 8% to 2% among cohorts already receiving zidovudine (as is the current goal of the pediatric ACTG).

In the United States, 7% of pregnant women receive little or no prenatal care; however, some groups, such as African Americans and Hispanics, have rates closer to 10%. Often their first and only opportunity to have counseling and testing for HIV occurs when they are admitted during labor. Women who have inadequate care are often at particular risk for HIV infection because of drug use. For example, a study[8] conducted at a municipal hospital in New York in 1989 found that 50% of the deliveries to HIV-infected women occurred among the 15% of women with neither a prenatal nor a delivery care. Those percentages will vary widely by region (17.9% of African Americans in the District of Columbia had prenatal care[9] and temporally with the ebb and flow of drug epidemics, resulting in differences in the relative contribution that intrapartum HIV counseling and testing and, where indicated, intrapartum prophylaxis could potentially make to reductions in mother-to-child transmission rates.

In situations such as the one cited above (where 50% of HIV-infected women have no antenatal testing), if intrapartum therapy reduced transmission by one third as opposed to the two thirds associated with the full ACTG (076 regimen), more children would be spared HIV disease than would be spared by the development of more advanced therapeutics that can reduce the rate of transmission to 2% or less. Clearly, if the effectiveness of intrapartum and neonatal zidovudine more closely approximated that of a full prenatal intrapartum...
Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings
National Recommendations for HIV Testing of Pregnant Women
CDC (USPHS) and ACOG

- Prenatal: routine, universal HIV screening with the right to decline
- 3rd trimester: repeat if woman has risk factors, is in area of high prevalence, or has previously refused
- L&D: routine rapid testing for women with unknown HIV status
- Postnatal: rapid testing for infants whose mother’s status is unknown
- State regulations, laws, policies about HIV screening of pregnant women vary
Recommendations for Third Trimester Repeat HIV Testing

- In jurisdictions with an elevated incidence of HIV/AIDS among women
- Women known to be at high risk for HIV
- Facilities that identify HIV infection in at least 1/1,000 women screened
- Women who have signs or symptoms of acute HIV infection (retroviral syndrome)
Recommendations for Third Trimester Repeat HIV Testing

- In jurisdictions with an elevated incidence of HIV/AIDS among women
- Women known to be at high risk for HIV
- Facilities that identify HIV infection in at least 1/1,000 women screened
- Women who have signs or symptoms of acute HIV infection (retroviral syndrome)
Terminology

*Opt-out screening:* performing an HIV test after notifying the patient that the test will be done; consent is inferred unless the patient declines
## Current ACOG & CDC Recommendations: General Similarities & Differences

<table>
<thead>
<tr>
<th>Recommendation*</th>
<th>CDC</th>
<th>ACOG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opt-out HIV screening early in PNC</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Repeat HIV testing in 3rd trimester for women:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- in jurisdictions/states with elevated HIV incidence among women ages 15-45</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>- in elevated prevalence health care facilities</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>- known to be at high risk for HIV-infection</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>- who declined earlier HIV testing</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

*Some differences in specific terms used*
<table>
<thead>
<tr>
<th>Recommendation*</th>
<th>CDC</th>
<th>ACOG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opt-out rapid HIV testing for women in labor with undocumented HIV test during this pregnancy</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>- initiate ARV prophylaxis on basis of rapid test result</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Rapid HIV testing of newborn if mother’s HIV status unknown.</td>
<td>+</td>
<td>*</td>
</tr>
<tr>
<td>Document if HIV testing declined</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

*Some differences in specific terms used
MIRIAD Sites and Hospitals

Chicago
- Cook County
- Bethany
- St. Bernard
- Provident
- Mt. Sinai
- University of Chicago

New York
- Bronx-Lebanon
- Harlem
- Jacobi
- N. Central Bronx
- Lincoln

Atlanta
- Grady

Louisiana
- Charity (New Orleans)
- Earl K. Long (Baton Rouge)

Miami
- Jackson Memorial
- Jackson North
- Jackson South
Objectives of MIRIAD

Mother Infant Rapid Intervention At Delivery

- To determine the feasibility and performance of rapid HIV testing for women in labor with undocumented HIV status
- To provide timely antiretroviral drug prophylaxis to reduce perinatal transmission
- To facilitate follow-up care for HIV-infected women and their infants
MIRIAD Eligibility & Acceptance 2001-2005

- 153,014 visits evaluated at 17 hospital L&D units
- 12,481 (8.2%) women were eligible to participate
  - 38% had no prenatal care
- 9,233 (74%) offered MIRIAD (rapid HIV testing)
- 7,898 (86%) consented for participation/testing

Acceptance rates varied:
- 87.2% using residual from other labs vs.
- 73.9% when additional finger stick required.
  (p<0.0001)

MIRIAD Participants, 2001-2005

Women with BOTH rapid test & EIA results available
N=7753

HIV+ women
52 (0.7%)

HIV- women
7701 (99.3%)

2 women without delivery information

50 deliveries;
51 babies

HIV+ infants
5/43 (12%)

HIV - infants
38/43 (88%)

Infant HIV status unknown: 8

25/52 (48%) did not disclose known HIV infection
### Turnaround Times for Rapid Test Results, Point-of-Care vs. Lab Testing: MIRIAD 2001-2005

<table>
<thead>
<tr>
<th>Activity</th>
<th>Point of Care</th>
<th>Laboratory</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arrival on L&amp;D to result to woman</td>
<td>242 min</td>
<td>295 min (4hrs, 45min)</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Blood Drawn to result to provider</td>
<td>30 min</td>
<td>68 min</td>
<td>p&lt;0.0001</td>
</tr>
</tbody>
</table>

OraQuick Performance, MIRIAD, 2001-2005
7753 women tested

<table>
<thead>
<tr>
<th># False positives</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>EIA: 18 false positives</td>
<td></td>
</tr>
<tr>
<td># False negatives</td>
<td>0</td>
</tr>
<tr>
<td>Sensitivity (95% CI)</td>
<td>100%</td>
</tr>
<tr>
<td>Specificity (95% CI)</td>
<td>99.9% [EIA: 99.77%]</td>
</tr>
<tr>
<td>Positive Predictive Value</td>
<td>52/58 (90%) [EIA: 52/70 (74%)]</td>
</tr>
</tbody>
</table>

MIRIAD Study Summary: Intrapartum

Intrapartum rapid HIV testing of women with unknown status is feasible, acceptable, and accurate.

Giving a Pregnant Woman Negative HIV Test Results

- Meaning of a negative test result: “Your HIV test was negative...you are not infected with HIV...the test may not detect recent infection.”
- Refer women at risk for HIV infection for counseling and risk-reduction interventions
- Repeat HIV testing in 3rd trimester in areas or jurisdictions of high HIV prevalence or for women with risk factors
The Rapid Test is Positive
The Rapid Test is Positive

- Disclosure
  - Gently, privately – tailor counseling for setting (L&D vs. outpatient)

- Final results await confirmatory testing

- For women in labor, review & initiate ARV prophylaxis
Counseling a Pregnant Woman with a Positive HIV Test

- Meaning of a positive test result:
  “Your HIV test was positive. This means you have HIV infection.”

- “The important thing to know is that there is treatment for HIV that can help your health and reduce the risk of transmission to your baby.”

- Focus on woman’s feelings, immediate support system
  “Do you have someone you can talk to about this?”
Positive HIV Results (continued)

- Referral for HIV care/consult with HIV/OB expert
  - Evaluation for ARV treatment
  - ARVs for preventing perinatal transmission

- Referral for post-test counseling and partner services

- Reinforce that there is treatment for her and for reducing the risk to her baby
The Rapid Test is Positive

- Mode of delivery-vaginal but?
- No invasive uterine procedures, including forceps or vacuum
- Avoid amniotomy
- Follow-up care
  - Mother and baby
HIV Prophylaxis to Prevent Perinatal Transmission in Labor/Newborn Positive Rapid Test

Start Intravenous AZT/ZDV immediately plus 6 weeks of oral AZT/ZDV for the infant.

Some experts would add additional ARVs, consider consultation with infectious disease.

www.aidsinfo.nih.gov
Will the annual number of perinatal HIV infections decline without additional effort and expense?

- Annual number of HIV-exposed births is increasing (30% increase from 2000 to 2006)
- Hardest-to-reach HIV-infected women & their infants pose an ongoing, significant challenge
- Evidence suggests that the annual number of HIV-infected infants is stable or increasing
Estimated number of births to women living with HIV infection, 2000-2006

2006 estimate (8,650 – 8,900) is ~30% > 2000 estimate (6,075 – 6,422)

Office of Inspector General (Fleming), 2002
Whitmore, et al. CROI, 2009
Missed Opportunities- Enhanced Perinatal Surveillance 1999-2008, 26 sites

<table>
<thead>
<tr>
<th>Missed opportunity</th>
<th>HIV-exposed infants* N=12,136 (100%)</th>
<th>HIV-infected infants n=753 (6.2%)</th>
<th>HIV-uninfected Infants n=11,383 (93.8%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No prenatal care</td>
<td>944 (7.8%)</td>
<td>124 (16.5%)</td>
<td>820 (7.2%)</td>
</tr>
<tr>
<td>No maternal HIV test</td>
<td>582 (4.8%)</td>
<td>175 (23.2%)</td>
<td>407 (3.6%)</td>
</tr>
<tr>
<td>No prenatal ARVs</td>
<td>1693 (14.0%)</td>
<td>377 (50.1%)</td>
<td>1316 (11.6%)</td>
</tr>
<tr>
<td>No L&amp;D ARVs</td>
<td>1487 (12.3%)</td>
<td>273 (36.3%)</td>
<td>1214 (10.7%)</td>
</tr>
<tr>
<td>≥ 1 missed opportunity</td>
<td>2594 (21.4%)</td>
<td>444 (59.0%)</td>
<td>2150 (18.9%)</td>
</tr>
</tbody>
</table>

*HIV-exposed singleton births with known HIV status

Many areas without supplemental perinatal prevention funding not included.

CDC, unpublished data.
Prevention of Perinatal HIV Transmission in the United States
CDC Consultation, April 2008

- Experts in:
  - public health prevention programs, epidemiology & surveillance, HIV medicine, obstetrics, pediatrics
- From:
  - federal agencies, academic institutions, professional medical associations, advocacy organizations

**Consensus:**
Elimination of perinatal HIV transmission is possible and it should be a goal in the United States.
Elimination of Perinatal HIV Transmission—Goal Proposed by Consultants

- Incidence < 1/100,000 live births
  - < 40 cases annually among a 4 million birth cohort
- Transmission Rate < 1%
  - e.g., < 87 cases in 2006 (8700 HIV-exposed births)

Both goals represent a reduction of >100 cases per year.
Reproductive health and family planning services, preconception care, and universal HIV testing are essential components of EMCT and facilitate comprehensive real-time case finding of all HIV-infected pregnant women. Real-time case finding enables: comprehensive clinical care and social services for women and infants; detailed review of select cases to identify and address missed prevention opportunities and local systems issues through continuous quality improvement; research and long-term follow-up to develop and ensure safe, efficacious interventions for EMCT; thorough data reporting for HIV surveillance and EMCT evaluation.
Francois-Xavier Bagnoud Center
National Resource Center
University of Medicine & Dentistry of New Jersey

- Capacity building, training and technical assistance
- Information dissemination of clinical and training resources
- Development of patient education and clinician support materials for routine HIV testing

www.fxbcenter.org        www.aids-etc.org
FXB Center – AETC National Resource Center

- Centralizes training and clinical materials through a virtual library: www.aidsetc.org
- Capacity building, training and technical assistance
- Information dissemination of clinical and training resources
- Development of patient education and clinician support materials for routine HIV testing
Perinatal Hotline--National Perinatal HIV Consultation and Referral Service

...offers around-the-clock advise on testing and care of HIV-infected pregnant women and their infants

...provides referral to HIV specialists and regional resources

1-888-448-8765
- Clinical Guidelines for Antiretroviral Treatment
  - Adults and Adolescents
  - Pediatrics
  - Perinatal/Mother-to-Child Transmission
  - Post Exposure Prophylaxis
- Offering information on AIDS treatment, prevention and research
- http://aidsinfo.nih.org
Conclusions

- Every case of perinatally-acquired HIV infection is a sentinel event and should be investigated and issues addressed.

- More infants are being born to HIV-infected women.

- All pregnant women must know their HIV status for their own health and to reduce perinatal transmission.

- Rapid testing provides a key opportunity to reduce the impact of missed prevention opportunities.
Choosing a Rapid HIV Test

HIV Rapid Tests

Uni-Gold Recombigen

Multispot HIV-1/HIV-2

Clearview Complete HIV 1/2

Reveal G3

OraQuick Advance

Clearview HIV ½ Stat Pak
CPT Modifier 92 – Rapid Tests

- Alternative Laboratory Platform Testing:

- When laboratory testing is being performed using a single use, disposable, analytical chamber, the service may be identified by adding modifier 92 to the usual laboratory procedure code (HIV testing 86701-86703).

FDA-approved Rapid HIV Tests

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Sensitivity (95% C.I.)</th>
<th>Specificity (95% C.I.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral fluid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OraQuick Advance</td>
<td>99.3 (98.4 – 99.7)</td>
<td>99.8 (99.6-99.9)</td>
</tr>
<tr>
<td>Whole blood</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Un-Gold Recombigen</td>
<td>100 (98.6 – 100)</td>
<td>99.7 (99.0 – 100)</td>
</tr>
<tr>
<td>Stat-Pak</td>
<td>99.7 (98.9 – 100)</td>
<td>99.9 (98.6 – 100)</td>
</tr>
<tr>
<td>Sure Check</td>
<td>99.6 (98.6 – 100)</td>
<td>99.9 (98.6 – 100)</td>
</tr>
<tr>
<td>Serum/Plasma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reveal G1</td>
<td>99.8 (99.2 – 100)</td>
<td>99.9 (98.6 – 100)</td>
</tr>
<tr>
<td>Multispot</td>
<td>100 (99.9 – 100)</td>
<td>99.9 (98.8 – 100)</td>
</tr>
</tbody>
</table>

OraQuick Advance HIV-1/2

- CLIA-waived for finger stick, whole blood, oral fluid
- Store at room temperature
- Screens for HIV-1 and 2
- Read time 20-40 minutes
- Shelf life: One year
Choosing a Rapid HIV Test

Uni-Gold Recombigen
- CLIA-waived for finger stick, whole blood
- Store at room temperature
- Screens for HIV-1
- Read time 10-12 minutes
- Shelf life: 1 year

Clearview Complete HIV 1/2
- CLIA-waived for whole blood
- Store at room temperature
- Screens for HIV-1 and 2
- Read time 15-20 minutes
- Shelf life: 2 years

Clearview HIV-1/2 Stat-Pak
- CLIA-waived for whole blood and fingerstick
- Store at room temperature
- Screens for HIV-1 and 2
- Read time 15-20 minutes
- Shelf life: 2 years

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Choosing a Rapid HIV Test

Reveal G3
- CLIA moderate complexity with serum, plasma
- Store at room temperature
- Perform test in 5 minutes
- Shelf life: 1 year

Multispot HIV-1/HIV-2
- CLIA moderate complexity with serum, plasma
- Refrigerate reagents
- Distinguishes HIV-1 from HIV-2
- Perform test in 15 minutes
- Shelf life: 1 year refrigerated, 3 months room temperature

CDC Rapid Testing Web Page
- Comparison and purchasing charts:
  www.cdc.gov/hiv/rapid_testing
Interpreting Rapid Test Results

For a laboratory test:

**Sensitivity:** Probability test=positive if patient=positive

**Specificity:** Probability test=negative if patient=negative

**Predictive value:**

Probability patient=positive if test=positive
Probability patient=negative if test=negative

Example: Test 1,000 persons
Test Specificity = 99.6% (4/1000)

HIV prevalence = 10%

<table>
<thead>
<tr>
<th>True positive</th>
<th>False positive</th>
<th>Positive predictive value</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>4</td>
<td>100/104 = 96%</td>
</tr>
</tbody>
</table>

STAT sample requests without pausing
Results in ~60 minutes
Example: Test 1,000 persons
Test Specificity = 99.6% (4/1000)

HIV prevalence = 10%
True positive: 100  False positive: 4
Positive predictive value: 100/104 = 96%

HIV prevalence = 0.4%
True positive: 4  False positive: 4
Positive predictive value: 4/8 = 50%

Positive Predictive Value of a Single Test
Depends on Specificity & Varies with Prevalence

<table>
<thead>
<tr>
<th>HIV Prevalence</th>
<th>Predictive Value, Positive Test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OraQuick</td>
</tr>
<tr>
<td>10%</td>
<td>99%</td>
</tr>
<tr>
<td>5%</td>
<td>98%</td>
</tr>
<tr>
<td>2%</td>
<td>95%</td>
</tr>
<tr>
<td>1%</td>
<td>91%</td>
</tr>
<tr>
<td>0.5%</td>
<td>83%</td>
</tr>
<tr>
<td>0.3%</td>
<td>75%</td>
</tr>
<tr>
<td>0.1%</td>
<td>50%</td>
</tr>
</tbody>
</table>

Test Specificity 99.9% 99.1% 99.7% 99.6%

PPV - Newborn Screening

Newborn screening
3.7 million infants screened

<table>
<thead>
<tr>
<th></th>
<th>Cases</th>
<th>Incidence</th>
<th>PPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>PKU</td>
<td>289</td>
<td>1:13,000</td>
<td>30%</td>
</tr>
<tr>
<td>Galactosemia</td>
<td>54</td>
<td>1:62,800</td>
<td>30%</td>
</tr>
<tr>
<td>Hypothyroidism</td>
<td>1203</td>
<td>1:3,300</td>
<td>30%</td>
</tr>
<tr>
<td>Adrenal Hypoplasia</td>
<td>51</td>
<td>1:25,100</td>
<td>30%</td>
</tr>
</tbody>
</table>

Arch Pediatr Adolesc Med. 2000
Choosing a Rapid HIV Test

Negative Predictive Value of a Single Test Depends on Sensitivity & Varies with Prevalence

<table>
<thead>
<tr>
<th>HIV Prevalence</th>
<th>Predictive Value, Negative Test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OraQuick</td>
</tr>
<tr>
<td>10%</td>
<td>99.96%</td>
</tr>
<tr>
<td>5%</td>
<td>99.98%</td>
</tr>
<tr>
<td>2%</td>
<td>100%</td>
</tr>
<tr>
<td>1%</td>
<td>100%</td>
</tr>
<tr>
<td>0.5%</td>
<td>100%</td>
</tr>
<tr>
<td>0.3%</td>
<td>100%</td>
</tr>
<tr>
<td>0.1%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Test Sensitivity 99.6% 99.8% 100% 100%

---

A1: Sensitive HIV-1/2 immunoassay
(e.g., 4th generation Ag/Ab assay)
A1+ HIV-1 +
HIV-1 antibodies detected
Initiate care
A1- Negative for HIV-1 and HIV-2 antibodies (and p24 Ag*)
A2 HIV-2 +
HIV-2 antibodies detected
Initiate care
A1&2 (-) HIV-1&2 (-) NAAT**
Acute HIV-1 infection
Initiate care
NAAT (-) Negative for HIV-1

---

Current Assays with 15 Seroconverter Panels

185 specimens from 15 seroconverters
- Owens et al, CDC unpublished data

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Choosing a Rapid HIV Test

On the Horizon…

Elements of a QA Program
1. Organization of the QA Program
2. Testing Personnel
3. Process Control:
   1. Before testing
   2. During testing
   3. After testing
4. Documents and Records
5. Troubleshooting

http://www.cdc.gov/hiv/topics/testing/healthcare

Remember the tradeoffs…
- Good News: More HIV-positive women learn their status earlier in their infection
  - Access life saving HIV care and treatment
  - Reduce the risk of transmission to others including children and partners
- Challenging News: Some people will receive a false-positive result before confirmatory testing.

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Resources

- Free online toolkit
- Includes:
  - Issues and resources
  - Chart highlighting which payers reimburse for what
  - Cost calculator
- www.hret.org/hiv-cost

Perinatal HIV Resources

- National HIV/AIDS Clinical Consultation Center at UCSF
  - Perinatal HIV Hotline/Clinical Network (888) 448-8765
  - Warmline (800) 933-3413
  - Post-Exposure Prophylaxis Hotline (888) 448-4911
  - State law updates www.nccc.ucsf.edu
Clinicians’ Needs

Information and expert consultation:
- HIV testing for pregnant women & infants
- Antiretroviral (ARV) drug use during pregnancy and labor & delivery
- Care of HIV-exposed newborns

Urgent consultation:
- Interpretation of rapid HIV tests in labor
- Management ARVs during labor & delivery
- Mode of delivery
- Initial PEP choice for exposed infants

Pregnant women and their infants also need referral to competent clinicians or consultants in their local areas.

To meet these needs...
National Perinatal HIV Consultation and Referral Service - 888-448-8765

Perinatal HIV Hotline
Advice on testing and care of HIV-infected pregnant women and their infants

Perinatal HIV Clinicians Network
Referral to HIV specialists and regional resources

Perinatal HIV Hotline
- Live consultation - 9 a.m. to 2 a.m. ET
- Staffed by MDs and PharmDs with expertise in perinatal HIV care
- Available to all health care providers
- Free of charge
- Confidential

Perinatal HIV Clinicians Network
- Perinatal HIV Hotline callers can be linked with local resources
  - For support, consultation, co-management or transfer of care for their patients
  - 290 network clinicians
- Coordinator: Shannon Weber, MSW
- sweber@nccc.ucsf.edu
- 888-448-8765
Perinatal HIV Clinicians Network

- HIV-experienced clinicians (OB, Nurse Midwife, Peds, FP, ID)
- Collaborating with existing local and regional networks of providers
Sample Call #1

Question: Need help now!

- 31 y.o. G2P1 at 32 weeks with no prior prenatal care and reported crack use presented to L & D delivery today with confirmed PPROM for 2 days. Patient is having contractions every 2-3 minutes. Received one dose of steroids.
- Rapid HIV test was sent on admission that has just been reported as positive.
- What are your recommendations?
**Sample Perinatal HIV Hotline Call #1**

- Perinatal Hotline's Answer:
  - Consider this a true positive
  - Send confirmatory Western Blot now.
  - Start IV AZT, oral 3TC and give a dose of nevirapine.
  - Dosages given.
  - Begin pitocin augmentation for expedited vaginal delivery.
  - Avoid scalp electrodes, instrumented delivery.
  - Start p.o. AZT for the infant
  - Mom should 'pump and dump' until confirmatory WB returns; if confirmed positive, baby should be formula fed.

**Sample Network Connections**

**Perinatal HIV Clinicians Network**

- A midwife in rural California called the Perinatal HIV Hotline regarding a 16 week pregnant patient whose routine HIV screening test and confirmatory tests returned positive.
- The midwife is in practice with an obstetrician. They are eager to learn how to treat HIV in pregnancy and would like to co-manage with an HIV specialist.
Perinatal HIV Clinicians Network

- We contacted clinicians within a two-hour radius of the patient, including an HIV/hepatitis specialty care nurse who travels bi-weekly with an infectious disease specialist to a clinic in the patient’s town.
- The midwife and specialty nurse agree on co-managed care for the patient, with regular calls from the midwife/obstetrician team to the Perinatal HIV Hotline.

Missed Opportunities: Case #1

- A couple wish to conceive.
- Both get tested and are HIV Ab negative.
- 3-4 months later they conceive.
- Mother was offered routine HIV testing at a prenatal visit but declined because “I just got tested” and “neither of us has had outside relations since we’ve been together.”

Missed Opportunities: Case #1

- Baby delivered full term and breast fed for one month
- Admitted at 3 months with respiratory distress, failure to thrive, thrush, axillary adenopathy, big liver
- Confirmed to have HIV, PCP and CMV
What were the missed opportunities?

- HIV test during pregnancy
- Rapid test on L&D
- ARV prophylaxis
- Formula feeding for infant

Missed Opportunities: Case #2

- 32 y.o. woman presented to care at 37 weeks
- HIV test returns positive
- ARV treatment given on emergent basis
- Infant is born 5 days later: HIV negative.
- Review of the mom’s medical chart revealed a positive HIV antibody test 2 years earlier during a previous pregnancy
Missed Opportunities: Case #2

- During previous pregnancy she presented similarly at 37 weeks and was tested for HIV.
- The results came back two weeks later, on the day she delivered at another hospital. Neither the patient nor the hospital were aware of her results.
- Her first child tested positive for HIV after her HIV status was rediscovered and disclosed in her second pregnancy.

What were the missed opportunities?

First pregnancy:
- HIV test results to patient, attending clinician, and L&D staff
- Rapid test on L&D
- ARV prophylaxis
- ARV for positive infant

Second Pregnancy:
- Adequate prenatal care
- Timely HIV test
- ARV prophylaxis
How Can the Perinatal HIV Hotline and Clinicians Network Help You?

- Telephone consultations
  - One time consultations, including second opinions about controversial issues
  - Follow patients
- Keep you informed of changes to the guidelines
- Send testing and treatment protocols
- Send materials, brochures, slides
- Help link patients with specialized local care through the Perinatal HIV Clinicians Network

How Can You Help the Perinatal HIV Hotline?

- Post Perinatal HIV Hotline telephone number in vital areas
- Promote the hotline and referral network at specialized and local conferences
- Participate in the Perinatal HIV Clinicians Network

Other Resources
Cultural Competency Resources

- HRET Disparities toolkit (collect data on race, ethnicity and primary language)
  - www.hretdisparities.org
- National Center for Cultural Competency (capacity building)
  - www11.georgetown.edu/research/gucchd/nccc

Cultural Competency (cont.)

- National Minority AIDS Council (coalition of CBOs)
  - www.nmac.org
- U.S. DHHS (resources for diverse populations)
  - AIDS Bureau
    - www.hab.hrsa.gov/special/culture.htm
  - Office of Minority Health
    - www.omhrc.gov

Cultural Competency (cont.)

- National Minority AIDS Education and Training Center (capacity building)
  - www.nmaetc.org
- AIDS Education and Training Centers National Resource Center
  - www.aidsetc.org
Resources (cont.)

- CDC’s One Test. Two Lives.
  - Campaign targeted at physicians and nurse-midwives to test for HIV. English and Spanish
  - www.cdc.gov/1test2lives


Materials

- Provider Materials
- Patient Brochure

Resources (cont.)

- Francois-Xavier Bagnoud Center
  - Perinatal HIV clinical support tools
    - www.fxbcenter.org
- University of Washington
  - HIV testing tutorial
    - http://depts.washington.edu/hivaids/
Resources (cont.)

- ACOG
  - Practice guidelines for ob-gyns
  - State legislative updates
    - [www.acog.org/goto/pHIV](http://www.acog.org/goto/pHIV)
- National Black Alcoholism and Addictions Council
  - HIV and substance abuse
    - [www.nbacinc.org](http://www.nbacinc.org)

Resources (cont.)

- HIV/AIDS Atlas
  - National Minority Quality Forum
  - Prevalence:
    - National
    - State
    - County
    - Legislative district
    - Zip Code (NYC only)
  - [http://maps.nmqf.org/atlas_login.aspx](http://maps.nmqf.org/atlas_login.aspx)
Future Opportunities

- Learning Collaboratives
  - Address common interests
  - Conference calls and in-person meetings

What Can You Share?

- HRET can serve as clearinghouse for:
  - Materials
  - Forms
  - Resources
“Sorry to bother you but my name is Hydeia Loren B and I am 24, I will be 25 in June and I was born with HIV which by the time I was tested turned into full blown AIDS and told I would not live past the age of 5. I was reading about your event online and I just wanted to say thank you for having this forum! …[E]vents like the one you are having are really meaningful to me and by having this event I know you will help save a child from being born with HIV!

Contact Information

- Joan M. Miller, MHA
  Health Research and Educational Trust (AHA)
  312-422-2619
  jmiller@aha.org
- Margaret Lampe, RN, MPH
  Centers for Disease Control and Prevention
  404-639-5189
  mol0@cdc.gov