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MCHB/DHSPS

March 2008

Preventing Mother to Child HIV
Transmission: Achieving Greater
Success in the United States

March 18, 2008



**Moderator:
Johannie Escarne**



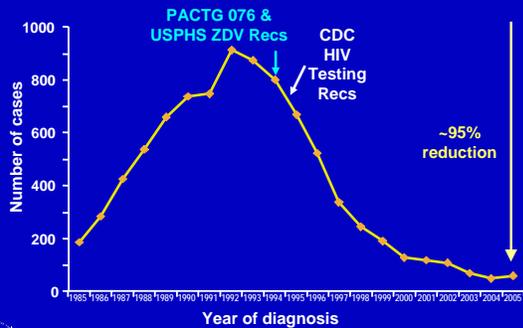
Preventing Mother to Child HIV Transmission: Achieving Greater Success in the United States

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

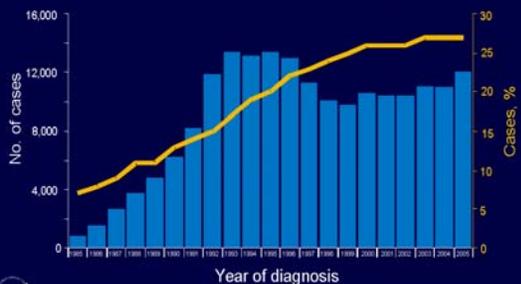
March 18, 2008

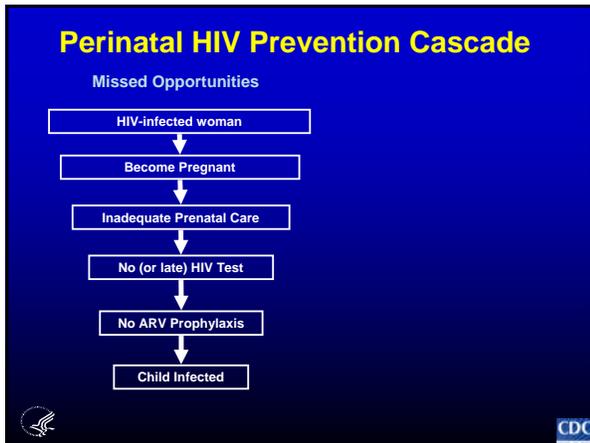


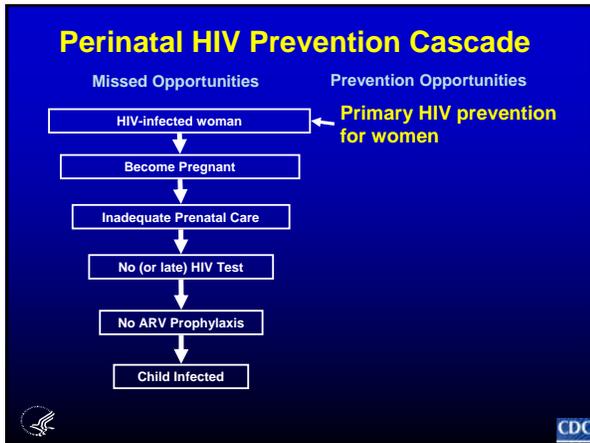
Estimated Number of Perinatally Acquired AIDS Cases, by Year of Diagnosis, 1985 – 2005 – United States



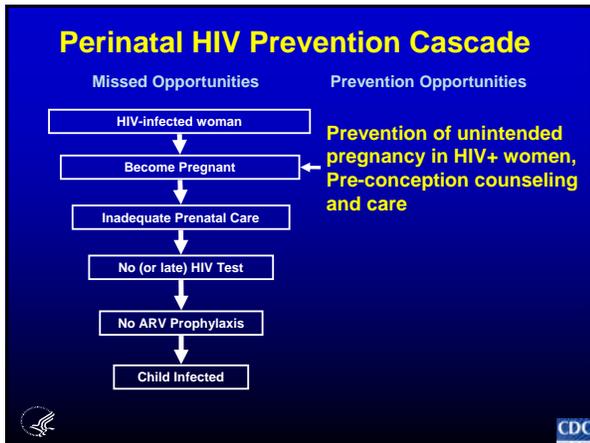
Estimated Number and Proportion of AIDS Cases among Female Adults and Adolescents 1985–2005—United States and Dependent Areas







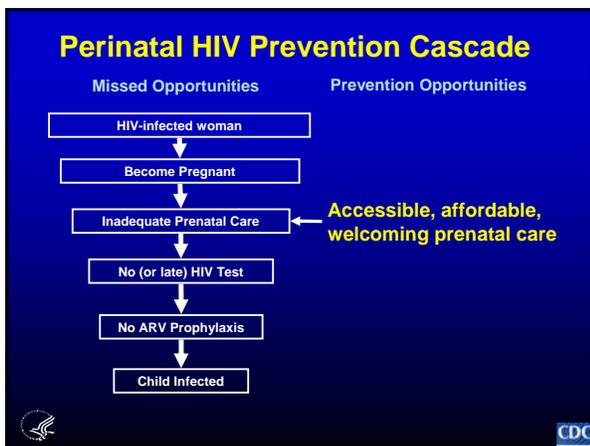
- ### Primary HIV prevention for women
- Reproductive and sexual health counseling
 - Routine, opt-out HIV screening in health care settings for adults and adolescents aged 15-64 in health care settings
-
- CDC

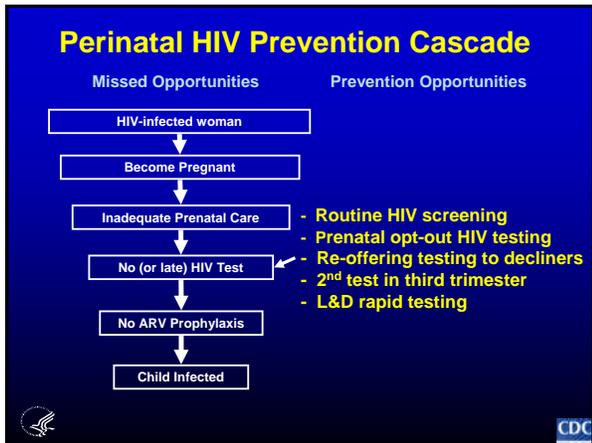


Preconception Counseling & Care for Women with HIV

Counsel and provide services:

- **Safe and effective contraceptive methods & reproductive options that prevent:**
 - HIV exposure to uninfected partners, and
 - exposure to STDs or more virulent or resistant HIV
- **Eliminate alcohol, illicit drugs & smoking**
- **HIV treatment (ARV) choices**
 - treat woman's HIV vs. risks to fetus
 - aim for stable, maximally suppressed viral load







Terminology

- **Diagnostic testing:** performing an HIV test based on clinical signs or symptoms
- **Targeted testing:** performing an HIV test on subpopulations of persons at higher risk based on behavioral, clinical or demographic characteristics
- **Screening:** performing an HIV test for all persons in a defined population
- **Opt-out screening:** performing an HIV test after notifying the patient that the test will be done; consent is inferred unless the patient declines

CDC

Revised Recommendations Adults and Adolescents - I

- Routine, voluntary HIV screening for all persons 13 and older in health care settings, not based on risk
- All patients with TB or seeking treatment for STDs should be screened for HIV
- Repeat HIV screening of persons with known risk at least annually
- When acute retroviral infection is a possibility, use an RNA test in conjunction with an antibody test



Revised Recommendations Adults and Adolescents - II

- Opt out HIV screening with the opportunity to ask questions and the option to decline testing
- Separate signed informed consent not recommended
- Prevention counseling in conjunction with HIV screening in health care settings is not required
- Communicate test results in same manner as other diagnostic/screening tests



Revised Recommendations Adults and Adolescents - III

- Settings with low or unknown prevalence:
 - Initiate screening
 - If yield from screening is less than 1 per 1000, continued screening is not warranted
- May need to resolve conflicts between the recommendations and state or local regulations



ACOG Recommendations, November, 2004



CDC & ACOG Recommendations for HIV Testing for Pregnant Women and Newborns:

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



*Some differences in specific terms used

22 Jurisdictions with elevated HIV or AIDS Case Rates Among Women aged 15-45, 2004*



≥ 17 HIV cases or ≥ 9 AIDS cases per 100,000 women includes Puerto Rico (not shown)



CDC & ACOG Recommendations for HIV Testing for Pregnant Women and Newborns:

Recommendation*	CDC	ACOG
Opt-out rapid HIV testing for women in labor with undocumented HIV test during this pregnancy	+	+
- initiate ARV prophylaxis on basis of rapid test result	+	+
Rapid HIV testing of newborn if mother's HIV status unknown.	+	

*Some differences in specific terms used



Role for Rapid HIV Tests

- Increase receipt of test results
- Increase identification of HIV-infected pregnant women so they can receive effective prophylaxis
- Increase feasibility of testing in acute-care settings with same-day results
- Increase number of venues where testing can be offered to high-risk persons



Uni-Gold Recombigen

Multispot HIV-1/HIV-2

OraQuick Advance

Clearview Complete HIV 1/2

Reveal G3

Clearview HIV 1/2 Stat Pak



OraQuick Advance HIV-1/2



- CLIA-waived for finger stick, whole blood, oral fluid; moderate complexity with plasma
- Store at room temperature
- Screens for HIV-1 and 2
- Results in 20 minutes

CDC



Collect oral fluid specimens by swabbing gums with test device.

Reduce hazards, facilitate testing in field settings

CDC



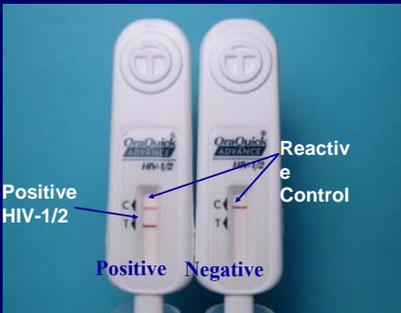
Insert device; test develops in 20 minutes





Insert device; test develops in 20 minutes





Read results in 20 – 40 minutes



Uni-Gold Recombigen



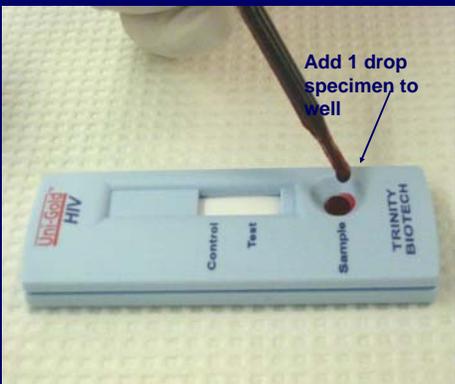
- CLIA-waived for finger stick, whole blood; moderate complexity with serum, plasma
- Store at room temperature
- Screens for HIV-1
- Results in 10 minutes

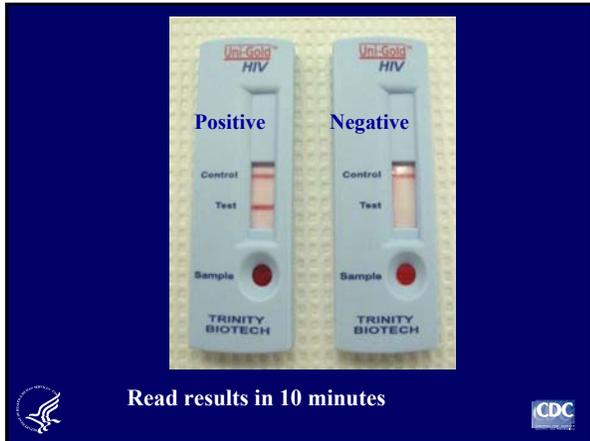




Finger stick with disposable pipette







Read results in 10 minutes



Clearview Complete HIV 1/2



- Whole blood, serum, or plasma
- Applied for CLIA waiver
- Room temperature storage
- Detects HIV-1 and 2
- Read results in 15-20 minutes





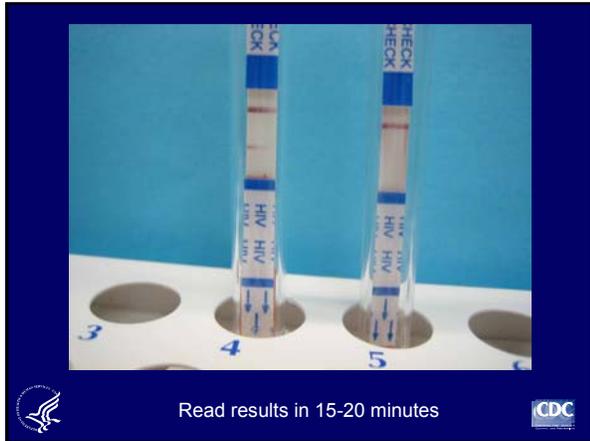
Obtain Fingerstick blood sample





Insert device into buffer vial





Read results in 15-20 minutes

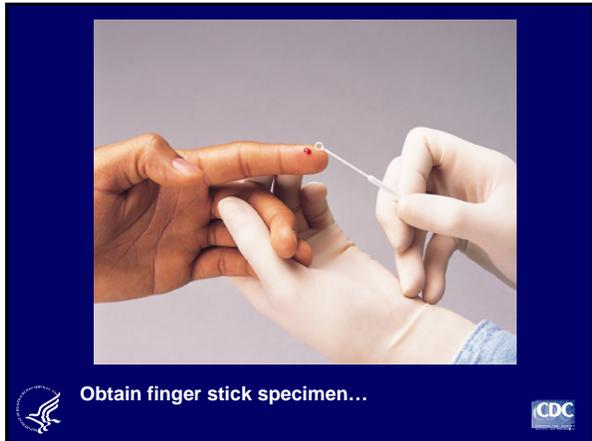


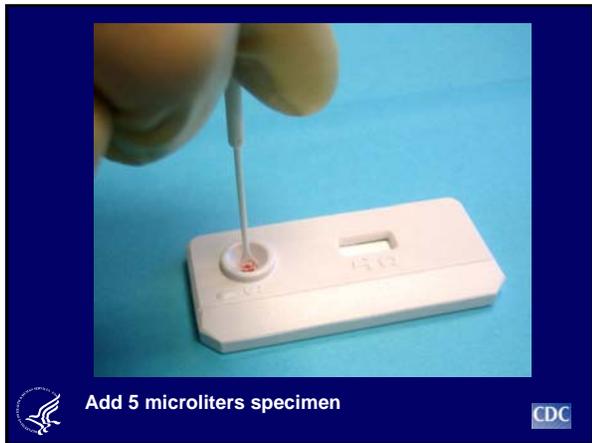
Clearview HIV-1/2 Stat-Pak



- Whole blood, serum, or plasma
- CLIA-waived
- Room temperature storage
- Detects HIV-1 and 2
- Read results in 15-20 minutes











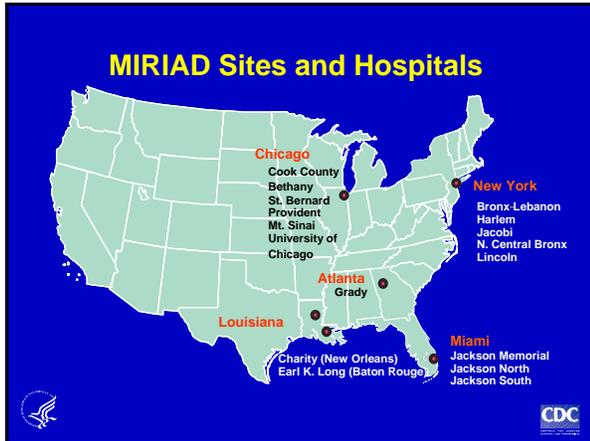
Rationale for Rapid HIV Testing for Women in Labor

- 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



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

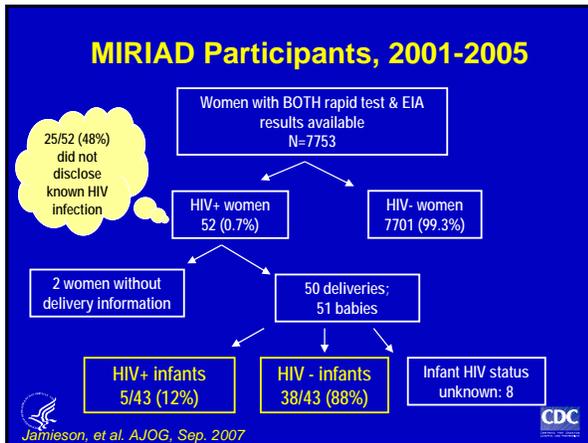
MIRIAD Eligibility & Acceptance 2001-2005

- 153,014 visits evaluated at 17 hospital L&D units
- 12,481 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)

Jamieson, et al. AJOG, Sep, 2007



OraQuick Performance, MIRIAD, 2001-2005

7753 women tested

# False positives	6 [EIA: 18 false positives]
# False negatives	0
Sensitivity (95% CI)	100% (93.15% – 100%)
Specificity (95% CI)	99.9% (99.83% – 99.97%)
Positive Predictive Value	52/58 (90%) [EIA: 52/70 (74%)]

Jamieson, et al. AJOG, Sep. 2007

CDC

Rapid HIV Antibody Testing During Labor and Delivery for Women of Unknown HIV Status
A Practical Guide and Model Protocol

CDC

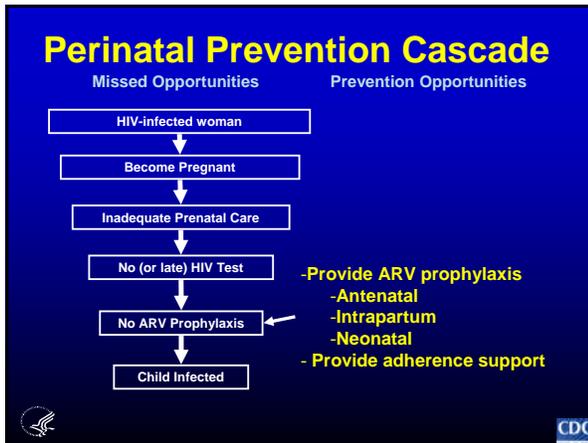
Practical guidance to:

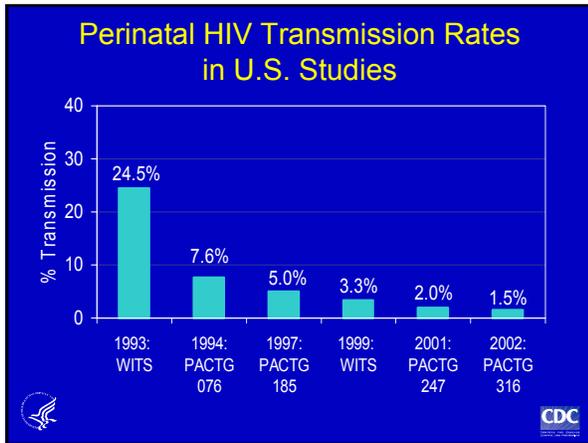
- Clinicians
- Laboratorians
- Hospital Administrators
- Public Health Professionals
- Policy Makers

Provide general structure of a rapid HIV testing protocol, can be adapted locally

Jamieson, et al. AJOG, Sep. 2007

CDC





- Use of ARVs
- Clinical trial data
- Preconception Counseling and Care
- Antepartum Care
- Intrapartum Care
 - Mode of delivery
- Postpartum Management
- Neonatal Care
 - ARV safety

CDC

General Clinical Management Principles

- Earlier diagnosis → better outcomes
- ARV drugs lower maternal viral load, and provide pre and post exposure prophylaxis to the infant
- Antepartum, intrapartum and neonatal ARVs
- Combination drugs are more effective than single drug regimens
- Starting ARVs by 28 weeks gestation is best
- ARVs to prevent PMCT for all HIV infected women, even with low viral load
- Counseling re: adherence is important to prevent resistance



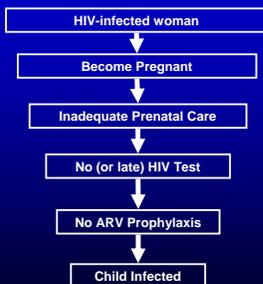
General Clinical Management Principles

- Goal is maximal reduction of viral load
- Intrapartum IV ZDV for all pregnant women
- Cesarean delivery with viral load > 1,000 copies/ml
- Initiate ZDV on a reactive rapid test, d/c if confirmed HIV uninfected
- Neonatal oral ZDV for 6 weeks, initiate ASAP after birth, within 12 hours
- **NO BREASTFEEDING!**
- Clinical expert consultation is important, and resources are available



Perinatal Prevention Cascade

Missed Opportunities Prevention Opportunities



Comprehensive services for mother and infant



Resources

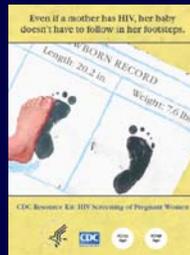
- ❑ National Model Protocol
www.cdc.gov/hiv/projects/perinatal/
- ❑ CDC HIV Testing in Health Care Settings
<http://www.cdc.gov/hiv/topics/testing/healthcare/>
- ❑ USPHS Treatment Guidelines
www.aidsinfo.nih.gov
- ❑ www.WomenChildrenHIV.org





One Test. Two Lives. 2007

- Campaign promoting prenatal HIV screening to providers & patients
- www.cdc.gov/1test2lives



One Test. Two Lives. Provider Materials



One Test. Two Lives. Patient Materials-English/Spanish



Thank You

mlampe@cdc.gov



Preventing Mother to Child HIV Transmission: Achieving Greater Success in the US

Shannon Weber, MSW
Perinatal HIV Hotline Coordinator

Maternal Child Health Bureau Webcast
March 18, 2008

sweber@ncccc.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



● ● ● Clinicians' Needs

Urgent consultation:

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



● ● ● Clinicians' Needs

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



National HIV/AIDS Clinicians' Consultation Center
 UCSF – San Francisco General Hospital

Perinatal HIV Hotline (888) 448 - 8765
 National Perinatal HIV Consultation & Referral Service
Advice on testing and care of HIV-infected pregnant women and their infants
Referral to HIV specialists and regional resources

Warmline (800) 933 - 3413
 National HIV Telephone Consultation Service
Consultation on all aspects of HIV testing and clinical care

PEPLINE (888) 448 - 4911
 National Clinicians' Post-Exposure Prophylaxis Hotline
Recommendations on managing occupational exposures to HIV and hepatitis B & C

HRSA AIDS ETC Program & Community Based Programs, HIV/AIDS Bureau & Centers for Disease Control and Prevention (CDC)

Perinatal HIV Hotline

- 24-hour, live consultation
- Staffed by MDs and PharmDs with expertise in perinatal HIV care
- Available to all health care providers
- Free of charge
- Confidential



<http://AIDSinfo.nih.gov>

Public Health Service Task Force
Recommendations for Use of Antiretroviral
Drugs in Pregnant HIV-Infected Women for
Maternal Health and
Interventions to Reduce Perinatal HIV
Transmission in the United States
 November 2, 2007

Replaces the October 13, 2006
 Public Health Service Task Force
 Recommendations for Use of Antiretroviral
 Drugs in Pregnant HIV-Infected Women
 for Maternal Health and Interventions to
 Reduce Perinatal HIV Transmission
 in the United States that have been made by the
 Perinatal HIV Outcomes Working Group.
 It is emphasized that concepts related to HIV management evolve
 rapidly. The Task Force has a responsibility to update recommendations
 on a regular basis, and the most recent information is available on the
 AIDSInfo Web site (<http://AIDSinfo.nih.gov>).

● ● ● **Calls to the Perinatal HIV Hotline**

**Consultation Needs in Perinatal HIV Care:
 Experience of the National Perinatal
 Consultation Service**

Fogler JA, Weber S, Goldschmidt R, Mahoney M,
 Cohan D. *Am J Obst Gynecology* 2007;S137-141

Perinatal HIV Hotline calls from
 January 1, 2005 – June 30, 2006

● ● ● **Perinatal HIV Hotline: Caller Profession**

Profession	Percentage
MD/DO	54.9%
<i>Family Medicine</i>	22.8%
<i>Infectious Disease</i>	30.6%
<i>Ob/Gyn</i>	25.0%
<i>Other MD/DO</i>	21.6%
NP/PA	15.5%
RN/LVN	12.8%
Other	16.8%
Total	100%

Data set 1/1/05-6/30/06



Perinatal HIV Hotline: Caller HIV+ Patient Load

HIV+ Patient Load	Percentage
1-10	19.5%
11-25	4.3%
26-50	7.9%
>50	26.6%
Unknown	33.8%
N/A	7.9%
Total	100%

Data set 1/1/05-6/30/06



Perinatal HIV Hotline: Caller Facility Type

Facility	Percent
Outpatient	53.7
Community Clinic	50.0
Private Practice	30.7
Other	19.3
Hospital	25.9
Hospital – L&D	32.9
Hospital – other	76.1
Other Medical	11.0
Nonmedical	7.0
Unknown	2.4
Total	100%

Data set 1/1/05-6/30/06



Perinatal HIV Hotline: Consultation Discussion Topics

Topic	Percent
Preconception/contraception	5.6
HIV care in pregnancy	49.1
HIV testing in pregnancy	21.9
Intrapartum HIV care	24.0
HIV-exposed infant care	29.1
General Information	14.7

*Topics add up to >100% because there may be multiple topics per call.

Data set 1/1/05-6/30/06

● ● ● 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
- 265 network clinicians

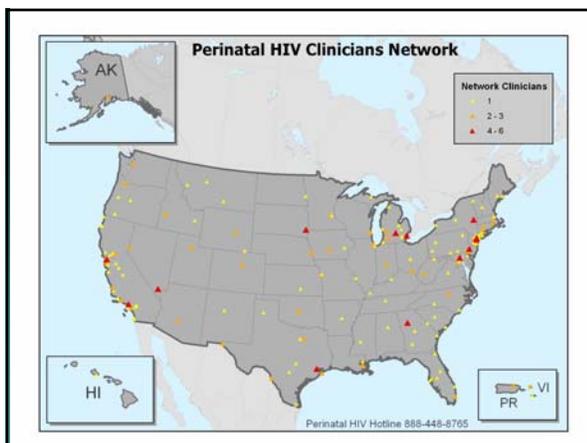
Coordinator: Shannon Weber, MSW
sweber@nccc.ucsf.edu
888-448-8765



● ● ● Perinatal HIV Clinicians Network

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







Sample Perinatal HIV Hotline Call #1

Perinatal HIV Hotline Call ID # 4199

Question: Is this patient HIV positive?

17 year old pregnant woman with positive ELISA and indeterminate Western Blot.

Tests repeated 6 weeks later with ELISA+ and Western Blot still indeterminate. Viral load was undetectable.

How to interpret?

Should this woman be started on ARVs?





Sample Perinatal HIV Hotline Call #1

Answer:

This patient is HIV-1 negative.

Pregnancy increases the number of false+ ELISAs.

Some people have polymorphisms that cause indeterminate Western Blots.

No need to start ARVs.





Sample Perinatal HIV Hotline Call #2

Perinatal HIV Hotline ID # 10290

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 #2**

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.



● ● ● **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?



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?



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





Perinatal HIV Resources

Health Research & Educational Trust (HRET)
<http://www.hret.org/hret/programs/hivtransm.html>

American College of Obstetrics and Gynecology (ACOG)
http://www.acog.org/departments/dept_notice.cfm?recno=39&bulletin=3529

FXB Center
www.fxbcenter.org





Perinatal HIV Resources

CDC
<http://www.cdc.gov/hiv/topics/perinatal/resources/factsheets/perinatal.htm>

Women, Children & HIV
<http://www.womenchildrenhiv.org/>



One Test. Two Lives.
www.cdc.gov/1test2lives



National HIV/AIDS Clinicians' Consultation Center
Warmline, PEPLINE, Perinatal Hotline
UCSF – San Francisco General Hospital

State HIV Testing Laws Compendium

www.ucsf.edu/hivcntr

- Descriptions of each state's HIV testing laws
- Definitions of commonly used terms
- Links to helpful resources

Health Resources and Services Administration (HRSA)
AIDS Education and Training Centers
and
Centers for Disease Control and Prevention (CDC)

Questions & Answers

Thank you for attending this event.

Please complete the evaluation directly following the webcast.

Archives of the event are located at
<http://www.mchcom.com>