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# **Adolescent HIV & Pregnancy:**

## **Advanced Management & Cases**

**Amanda Cotter MD MSPH**

**University of Miami Miller School of Medicine**

## **Objectives**

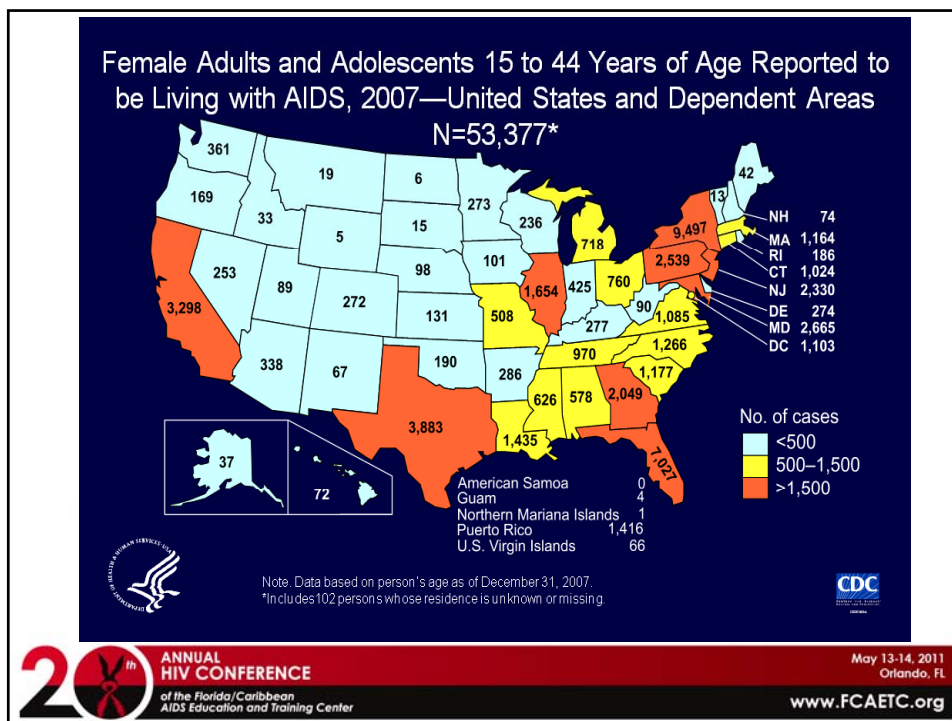
- **Discuss similarities & differences between pregnancy course & outcomes in vertically & horizontally infected adolescents**
- **Consider effective implementation of strategies to prevent perinatal HIV transmission in pregnant adolescents**
- **Compare the risks of & benefits of vaginal delivery & CS in HIV infected pregnant adolescents**
- **Provide advanced discussion of management of specific aspects of care in HIV infected pregnant adolescent**



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## Pregnancy & HIV Infection

- Most HIV infected women are of reproductive age
- 50% of pregnancies in the US are unplanned
- 150% ↑ in live birth rate among HIV+ women vs 5% ↑ HIV- women in era of HAART

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# Adolescent Pregnancies

400,000 deliveries/yr in USA

- PTL
- Anemia
- Hypertensive disorders
- LBW
- NND

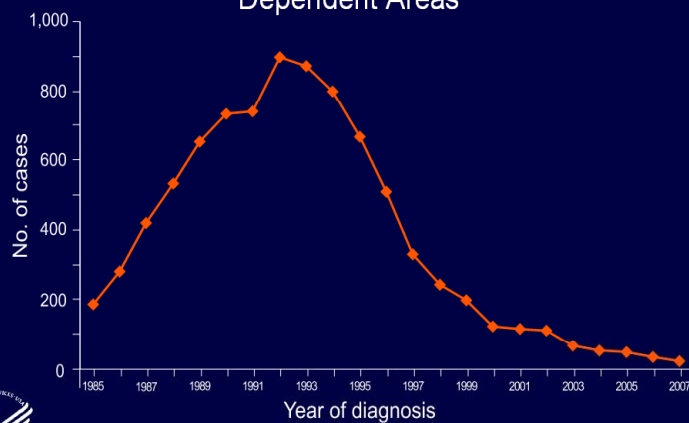


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Estimated Numbers of Perinatally Acquired AIDS Cases  
by Year of Diagnosis, 1985–2007—United States and  
Dependent Areas



Note: Data have been adjusted for reporting delays and missing risk factor information.



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## REDUCTION OF MATERNAL-INFANT TRANSMISSION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 WITH ZIDOVUDINE TREATMENT

EDWARD M. CONNOR, M.D., RHODA S. SPERLING, M.D., RICHARD GELBER, Ph.D., PAVEL KISELEV, Ph.D.,  
GWENDOLYN SCOTT, M.D., MARY JO O'SULLIVAN, M.D., RUSSELL VANDYKE, M.D., MOHAMMED BEY, M.D.,  
WILLIAM SHEARER, M.D., Ph.D., ROBERT L. JACOBSON, M.D., ELEANOR JIMENEZ, M.D.,  
EDWARD O'NEILL, M.D., BRIGITTE BAZIN, M.D., JEAN-FRANÇOIS DELFRAISSY, M.D., MARY CULNANE, M.S.,  
ROBERT COOMBS, M.D., Ph.D., MARY ELKINS, M.S., JACK MOYE, M.D., PAMELA STRATTON, M.D.,  
AND JAMES BALSLEY, M.D., Ph.D.,

FOR THE PEDIATRIC AIDS CLINICAL TRIALS GROUP PROTOCOL 076 STUDY GROUP\*



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## Mortality of Perinatal Infection

### Rate of Progression to Category C

- Children born 1985-1988: 25%
- Children born 1995-1999: 5%

European Collaborative Study

### Decrease Mortality a/w Combination Tx

- 1996-1999: 5.3% → 0.7%

PACTG 219



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## HIV Infected Adolescents

- Adolescents aged 13-19 years with HIV/AIDS in USA n=5678
- STIs 12% and abnormal cervical cytology 47.5% PACTG 219C
- Case report 1998
- Case series MMWR 2002
- Case series AJOG 2009



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## Reproductive Health of Adolescent Girls Perinatally Infected with HIV

- 47.5% had abnormal cervical cytology
- Sexually active girls less likely to be on ART than non sexually active girls
- Condyloma & trichomonas most frequent genital infections

Brogly 2007



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## Reproductive Health of Adolescent Girls Perinatally Infected with HIV

- 17% experienced a first pregnancy by age 19 years
- 7 had additional pregnancies
- 32 live births
- All received ART in pregnancy
- PNT rate 3.3%

Brogly 2007



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## Perinatally Infected Adolescents: Social & Behavioral Characteristics

Left school pre-pregnancy	38%
Had pregnant friends before own pregnancy	63%
Had STI pre-pregnancy	25%
> 1 sex partner	75%
Consistent condom use	25%
Always discussed HIV status with sex partner	62%
Had HIV + sex partners	13%

Zorilla et al MMWR 2002



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### HIV Infected Women Delivering at UM/JMH Medical Center

	2005	2006	2007	2008	2009	2010
Women delivered	139	146	153	148	122	90
VL<1000 %	84	83	88	83	92	83
CS %	69	67	71	55	76	72
BTL %	26	27	29	21	30	30
MTCT	0	0	0	0	0	1



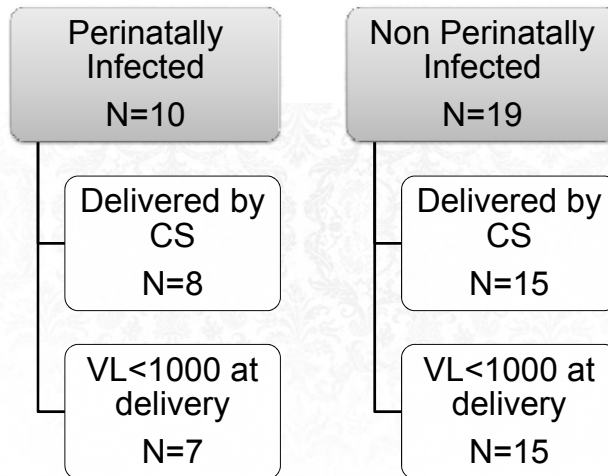
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# Adolescent Pregnancies 2010: The Miami Experience



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	Williams et al (2009)	Chibber et al (2005)	University of Miami/JMH	p-value
N	13	30	37	
Maternal age at delivery Mean (range)	19.8 (16-27)	18 (15-22)	19.8 (14-25)	0.074
Gestational age at delivery Mean (range)	37.3 (33-41)	38.5 (35-40)	37.4 (31-39)	0.262
Initial CD4 count Mean (range)	314 (2-858)	248 (52-996)	303 (1-642)	0.588
CD4 count at delivery Mean (range)	Unknown	220 (19-980)	335 (27-1043)	0.076
Initial viral load Mean (range)	71,597 (50-750,000)	15,700 (4,200-58,571)	14,998 (48-125,626)	0.113
Viral load at delivery Mean (range)	9,631 (50-48,042)	16,383 (6,535-65,571)	2,459 (48-36,382)	<b>0.003</b>
Birthweight Mean (range)	Unknown	3,072 (2,622-3,522)	2,793 (1,232-3,440)	<b>0.025</b>
Delivery by C/S (%)	61.5	3.3	73.0	<b>&lt;0.001</b>
Maternal comorbidities (%)	53.8	Unknown	18.9	<b>0.029</b>
2 <sup>nd</sup> Generation perinatal HIV infection (%)	7.7	0	0	<b>0.086*</b>
Low birthweight (%)	38.4	0	18.9	<b>0.003*</b>



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# Perinatal Infection & Pregnancy Outcomes: The Miami Experience

Parameter	University of Miami/JMH
Race (%)	
White	18.2
Black	81.8
AIDS (%)	10.8
ARV therapy prior to pregnancy (%)	10.8
Documented ARV resistance (%)	2.7
Mean Duration of ARV therapy (wks)	23
ARV therapy ZDV + Combivir + PI regimen (%)	91
Preeclampsia (%)	
None	81.1
Mild	13.5
Severe	5.4
Diabetes (%)	2.7
PPROM (%)	5.4



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## Preconceptional Counseling: Recommendations

- Discuss reproductive options
- Assess pregnancy intentions on ongoing basis
- Refer to experts



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## Preconception Counseling

- Impact of HIV on pregnancy, pregnancy on HIV progression, ARV treatment on pregnancy
- Maternal risk factors: drug/alcohol use, comorbid conditions
- General pregnancy issues
- Guardianship issues
- Risk, prevention of perinatal transmission
- Discussion of assisted reproductive technologies with the HIV-treating provider and the OB/GYN

Adapted from: Anderson J. A Guide to the Clinical Care of Women With HIV/AIDS. 2005. Chapter VII

- **Offer effective and appropriate contraceptive options to reduce likelihood of unintended pregnancy**
- **Be aware of potential interactions with ART which could lower efficacy**

## NNRTI and Hormonal Contraceptives

ART	Effect on Drug Levels	Clinical comment
Efavirenz	EE ↑ 37%	Clinical significance unknown
Etravirine	EE ↑ 22% NE no significant effect	No dosage adjustment necessary
Nevirapine	EE ↓ 20% NE ↓ 19% Depo no change	Use alternative or additional methods No dosage adjustment needed



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## Ritonavir Boosted PI & Hormonal Contraceptives

Atazanavir	EE ↓ Norgestimate ↑	Minimum dose 35 mcg EE
Darunavir	EE ↓ 44% NE ↓ 14%	Use alternative or additional method
Fosamprenavir	EE ↓ 37% NE ↓ 34%	Use alternative or additional method
Lopinavir	EE ↓ 42% NE ↓ 17%	Use alternative or additional method
Saquinavir	EE ↓	Use alternative or additional method
Tipranavir	EE ↓ 48% NE no change	Use alternative or additional method



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## PI Without Ritonavir & Hormonal Contraceptives

<b>Atazanavir</b>	EE ↑48% NE ↑110%	Max 30mcg EE
<b>Fosamprenavir</b>	EE ↑ NE ↑ Amprenavir ↓20%	Use alternative
<b>Indinavir</b>	EE ↑25% NE ↑26%	No dose adjustment
<b>Nelfinavir</b>	EE ↓47% NE ↓18%	Use alternative or additional method



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## CCR-5 Antagonist & Hormonal Contraceptives

<b>Maraviroc</b>	No significant effect on EE or levonorgestrel	Safe to use in combination
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- Educate and counsel about risk factors for PNT
- Strategies to reduce those risks
- Potential effects of HIV or treatment on pregnancy course and outcomes
- Advise re breastfeeding

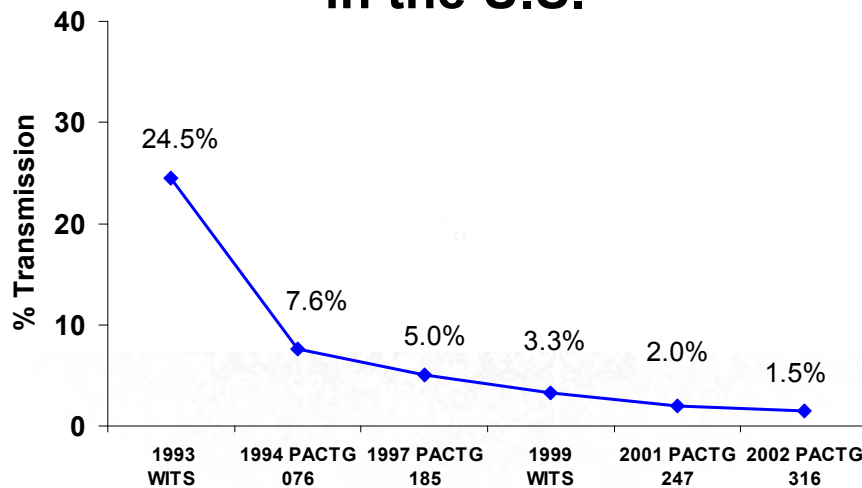


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## Mother to Child HIV Transmission in the U.S.



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## Possible Routes of Transmission



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## Risk Factors for Transmission in Era of Antiretroviral Therapy:

**Viral Load**  
**Type of Antiretroviral Therapy**  
**Mode of Delivery**

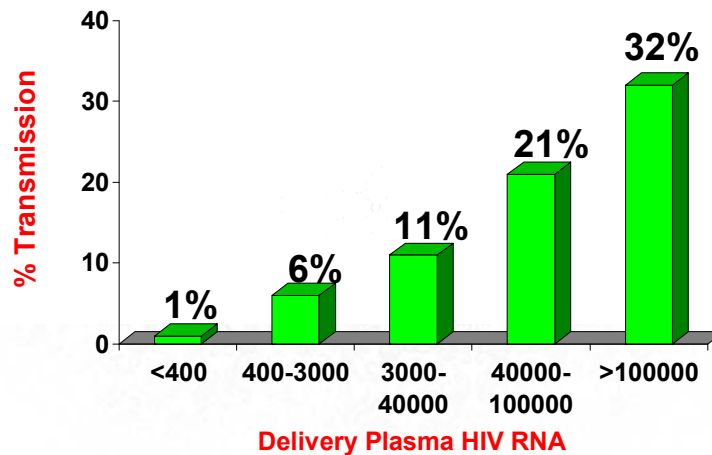


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## Delivery VL & Perinatal Transmission



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## Perinatal HIV Transmission and Maternal HIV RNA Viral Load

- Correlation between maternal VL and risk of transmission even in pregnant women treated with ARV agents
- Risk of transmission with VL ND is extremely low but transmission has occurred at all VL levels
- ZDV decreases transmission regardless of VL level

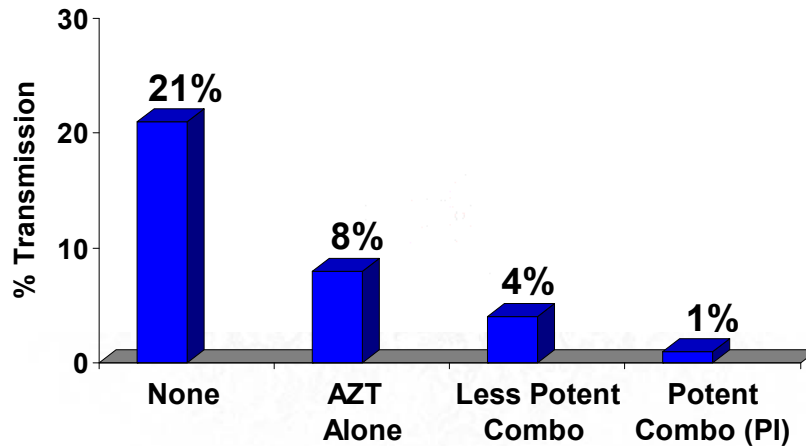


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## More Potent Antiretroviral Regimens associated with Lower Perinatal Transmission



Women & Infants Transmission Study, 1990-1999



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- Consider when prescribing ART effectiveness for treatment of HIV
- Hepatitis B status
- Potential for teratogenicity should pregnancy occur
- Possible adverse outcomes for mother and fetus



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- Use preconception time period for adjustment of ART regimens to exclude efavirenz or other drugs with teratogenic potential for women contemplating pregnancy



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- For adolescents who are on ART for their own health and who want to get pregnant, set attaining a stable maximally suppressed maternal viral load prior to conception as a primary treatment goal for her own wellbeing and to decrease risk of MTCT



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- Evaluate and appropriately manage therapy associated side effects that may adversely impact maternal fetal health outcomes eg hyperglycemia, anemia, hepatotoxicity



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- Evaluate need for appropriate prophylaxis or treatment for OIs including safety, tolerability and potential toxicity of specific agents when used in pregnancy



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## Administer medical immunizations as indicated

- Influenza
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- Hepatitis A
- Hepatitis B



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- Encourage sexual partners to receive HIV testing, counseling and appropriate care if HIV infected



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## Antepartum Care

- Review of prior HIV related illnesses, CD4 counts, VL & resistance studies
- Current CD4 count & VL
- Assess need for OI prophylaxis
- Baseline CBC, renal & liver profiles
- Hx prior ART
- Immunizations
- PPD

## Effects of ARV in Pregnancy

- Pregnant woman
- Fetus
- Newborn



## FDA Pregnancy Categories

A	Adequate well-controlled studies of pregnant women fail to demonstrate a risk to the fetus during first trimester (no evidence exists of risk during later trimesters).
B	Animal reproduction studies fail to demonstrate a risk to the fetus, and adequate but well-controlled studies of pregnant women have not been conducted.
C	Safety in human pregnancy has not been determined; animal studies are either positive for fetal risk or have not been conducted, and the drug should not be used unless the potential benefit outweighs the potential risk to the fetus.
D	Positive for human fetal risk that is based on adverse reaction data from investigational or marketing experiences, but the potential benefits from the use of the drug among pregnant women might be acceptable despite its potential risks.
X	Studies among animals or reports of adverse reactions have indicated that the risk associated with the use of the drug for pregnant women clearly outweighs any possible benefit.



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## ART Safety During Pregnancy

	B	C	D
NRTIs	Didanosine Emtricitabine Tenofovir	Abacavir Lamivudine Stavudine Zidovudine	
NNRTIs	Etravirine Nevirapine	Delavirdine	Efavirenz
Protease inhibitors	Atazanavir Darunavir Nelfinavir Ritonavir Saquinavir	Amprenavir Fosamprenavir Indinavir Lopinavir/r Tipranavir	
Entry inhibitors	Enfuvirtide Maraviroc		
Integrase inhibitor		Raltegravir	



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## Antiretroviral Agents in Pregnancy

	NRTI	NNRTI	Protease Inhibitor	Entry Inhibitor	Integrase Inhibitor
Recommended	Zidovudine Lamivudine	Nevirapine	Lopinavir/r		
Alternate	Didanosine Emtricitabine Stavudine Abacavir		Atazanavir Indinavir Nelfinavir Saquinavir HGC		
Insufficient data	Tenofovir	Efavirenz Etravirine	Darunavir Fosamprenavir Tipranavir	Enfuvirtide Maraviroc	Raltegravir
Not recommended		Delavirdine			



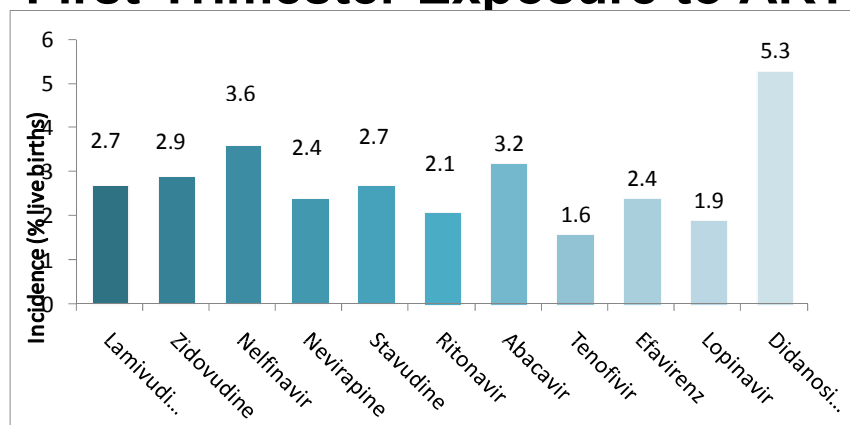
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## Prevalence of Birth Defects After First-Trimester Exposure to ART



Registry Coordinating Center. The Antiretroviral Pregnancy Registry Interim Report, December 2007. [http://www.apregistry.com/forms/interim\\_report.pdf](http://www.apregistry.com/forms/interim_report.pdf). Accessed April 9, 2008.



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## Infant Toxicities & ARV Exposure

- **Potential for**
  - mutagenic and carcinogenic effects
  - mitochondrial dysfunction
- **Zidovudine-related infant toxicity: anemia**
- **HIV-negative infants exposed in utero & neonatally have lower hematologic measurements than unexposed infants**



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## Special Considerations for ARV Use by Pregnant Women and Infants

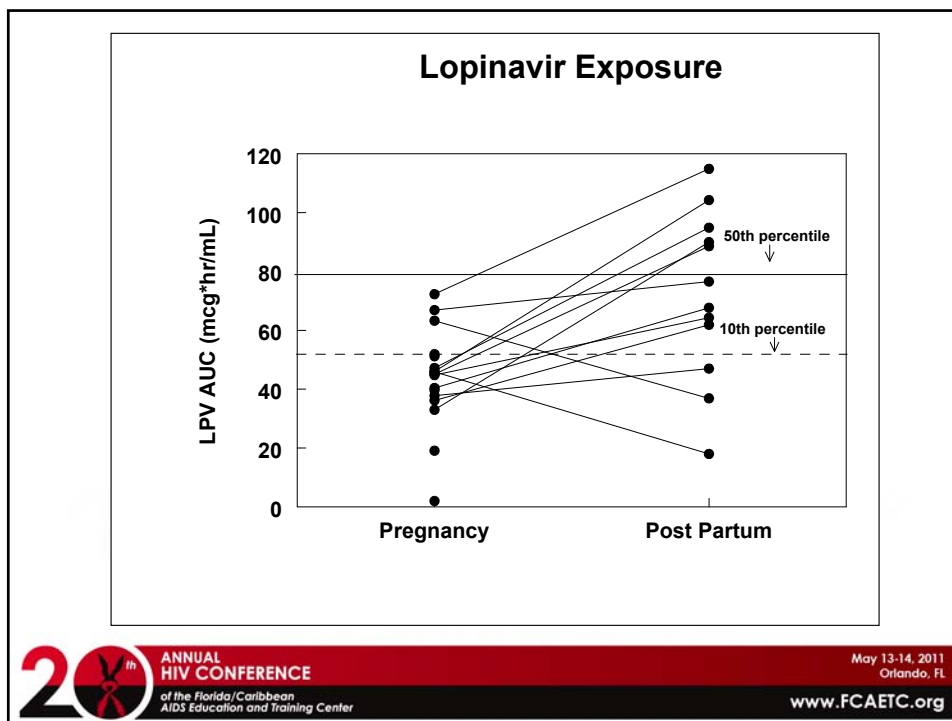
- **Pregnancy may alter ARV absorption, distribution and metabolism**
  - ARV dosing and toxicity risk may be affected
    - Some PIs may require altered dosing
- **Limited data to guide treatment in pregnant women**



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## Special Considerations for ARV Use by Pregnant Women and Infants

- **Potential adverse effects in pregnancy including teratogenicity**
  - Avoid during pregnancy:
    - Efavirenz – possible risk of NTDs
    - Nelfinavir – potential teratogenicity of ethyl methane sulfonate
    - Tenofovir – bone abnormalities in animal studies
    - Combination of d4T + ddI – increased risk of lactic acidosis and hepatic steatosis

## Special Considerations

- Use with caution during pregnancy:
  - Nevirapine – increased risk of hepatotoxicity; do not initiate in women with CD4 cell count  $>250$  cells/mm<sup>3</sup>
  - NRTIs: risk of lactic acidosis/hepatic steatosis; monitor LFTs, electrolytes monthly in 3rd trimester; assess often for new symptoms
- Screen for hyperglycemia:
  - Standard glucose loading test at 24 -28 weeks
  - Consider earlier screening if on chronic PI-based therapy

## ART and Pregnancy Outcome

- Conflicting data: are ARVs associated with adverse outcomes, especially PTD?
  - Most U.S. data do not demonstrate increased risk
- Conflicting data: does *in utero* ARV exposure cause mitochondrial dysfunction in neonates?
  - If true, appears to be very rare
- HIV-infected women should receive combination ARV therapy according to current guidelines

# Adverse Pregnancy Outcome

**Combination therapy was associated with a 33% risk of premature delivery**

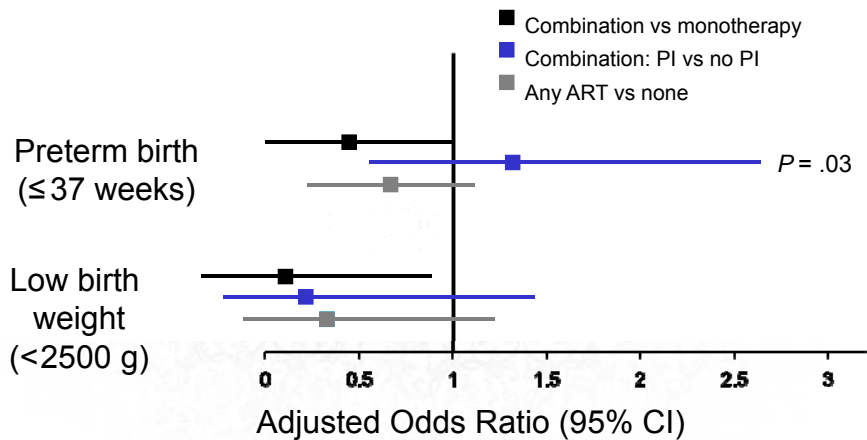
Lorenzi et al, AIDS 1998

# Adverse Pregnancy Outcome

- **No increase in preterm delivery, low birth weight or stillbirth**
- **5% on PI versus 2% had VLBW**

Tuomala et al, NEJM 2002

## Pregnancy Outcomes by ARV Regimen



Cotter et al. *J Infect Dis* 2006;193:1195-1201



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## ART & Risk of PTD

Combination therapy with a PI is associated with an increased rate of preterm delivery ( $p=0.0001$ )

OR 2.4, 95% CI 1.3 - 4.4

Cotter et al. *JID* 2006; 193: 1195



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# Intrapartum Care for HIV-Infected Women



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## Intrapartum ART/Prophylaxis

- **IV ZDV recommended for all HIV+ women during labor**
  - Continue other ARVs orally on schedule as possible
  - When administering ZDV, discontinue d4T
- **If suboptimal VL suppression on ARV, single-dose intrapartum maternal + infant NVP not recommended**
  - Cesarean delivery if VL >1,000 copies/mL



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- **Women with ZDV resistance should receive IV ZDV during labor, along with their ARV regimen**
  - Their infants should receive oral ZDV for 6 weeks
    - Often, only wild-type virus is transmitted
    - ZDV crosses placenta readily, with high levels in fetus
    - Reduces genital HIV VL
    - Consult pediatric HIV specialist



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## HIV Transmission & C/S

- **Scheduled C/S at 38 weeks to reduce risk of transmission:**
  - For women with HIV RNA levels >1000 copies/mL
  - For women with unknown HIV RNA levels
  - Benefits of C/S not clear after rupture of membranes or onset of labor
- **Benefits of C/S unclear for women with HIV RNA levels <1000 copies/mL**



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## Cesarean Delivery to Reduce Perinatal HIV Transmission

- Unclear whether scheduled C/S offers any benefit to women on ART with VL  $\leq$ 1000 VL copies/mL, given the low transmission rate
- Complications of C/S somewhat more frequent than in HIV-uninfected women
- Patient's decision should be respected

## Maternal Risks by Mode of Delivery

- Counsel women about potential risks and benefits of cesarean vs vaginal delivery
- C/S associated with greater risk of complications
- Complications do not outweigh benefits of reduced HIV transmission for those at increased risk
- Prophylactic narrow spectrum antibiotic generally recommended at time of C/S

# HIV-Infected Newborns 2005-2010

