

Perinatal HIV Transmission Prevention: Collaborative Success

Moderator: JoNell Potter, PhD, RN, ARNP

Presenters: Andrew Helfgott, MD
Robert M. Lawrence, MD
Carol M. Fulton, MSN, ARNP

Florida/Caribbean AETC

Disclosure of Financial Relationships

The speakers have only these significant financial relationships with commercial entities to disclose.

Robert M. Lawrence – none

Carole Fulton – none

JoNell Potter - none

Andrew Helfgott – Speakers Bureau Hologic Co
(Fetal Fibronectin)

This slide set has been peer-reviewed to ensure that there
are
no conflicts of interest represented in the presentation.

Learning Objectives:

- To increase practitioners **knowledge of new guidelines** and information concerning successful efforts of perinatal HIV transmission prevention programs
- To demonstrate the **use of practical tools** to guide prevention efforts and programs
- To model and **demonstrate collaboration** and partnership in preventive programs
- To provide attendees with additional **tools and guides** for the establishment and maintenance of effective perinatal HIV transmission prevention programs

Workshop Outline



- Introduction of presenters (2 minutes)
- Workshop objectives (2 minutes)
- Present new guidelines and information (12 minutes –A. Helfgott and R. Lawrence)
- Demonstrate useful tools for common issues (5 minutes –R. Lawrence)
- Model some examples of collaboration (14 minutes – C. Fulton and J. Potter)
- Questions and discussion (10 minutes - Group)

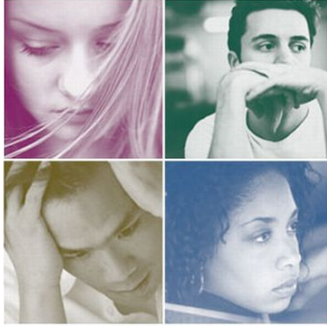
Presenters

- [Carol M. Fulton, BSN, MSN, ARNP](#)
- ARNP and CRNP in the Division of Pediatric Infectious Diseases and Rainbow Center at University of Florida Jacksonville, FL
- Ms Fulton is a part of the Florida/Caribbean AETC faculty & Courtesy Faculty for University of Florida, College of Nursing.
- She has been immersed in HIV care for 8 years as a Pediatric Nurse Practitioner for UF CARES, Rainbow Center for Women, Adolescents, Children and Families.
- She is actively involved in Perinatal HIV Prevention through direct patient care, education and technical assistance as part of the UF Rainbow Center and the Florida / Caribbean AETC missions.
- [JoNell Potter, RN, ARNP, Ph.D.](#)
- Associate Professor of Clinical Obstetrics/Gynecology and Nursing, and Director of the Research and Special Projects Division of the Department of OB/GYN at Univ. of Miami, FL
- She has 23 years of extensive research experience in women's health & HIV/AIDS and involved in the Perinatal HIV project since 1988.
- Dr. Potter has served as an investigator on several CDC sponsored multi-site projects, including the Mother Infant Rapid Testing at Delivery (MIRIAD) study, Project TEAM, and Adherence to HIV Guidelines for Pregnant Women.
- Dr. Potter has been an HIV provider in the South Florida community providing leadership for the implementation of primary care and early intervention services at the UM/JHS Medical Center.

Presenters

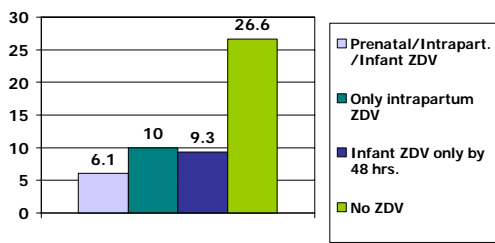
- [Robert M. Lawrence, M.D.](#)
- Clinical Associate Professor of Medicine, Pediatric Immunology and Infectious Diseases, University of Florida, Gainesville, Florida.
- He has cared for HIV infected children and adolescents since 1985, has participated in Pediatric AIDS Clinical Trials Group research.
- Dr. Lawrence has been the medical advisor to Children's Medical Services for Pediatric HIV in Florida since 2006.
- He cares for HIV-positive and HIV-exposed children in Gainesville, Panama City and Pensacola and 34 counties in Northwest Florida.
- [Andrew Helfgott, MD.](#)
- Professor and Chief of Obstetrics and Gynecology at the Medical College of Georgia, Augusta, GA.
- He began caring for Pregnant women in the 1990s at the University of Miami and continued at the Seton Center for High Risk Pregnancies at SHH in Pensacola, FL.
- Dr. Helfgott has been a member of the F/C AETC and continues as a consultant for HIV Care for Women before, during and after pregnancy.
- He continues to work directly with HIV-infected pregnant women and advocates for Perinatal HIV Transmission Prevention in Georgia and the Southeast United States.

Prevention



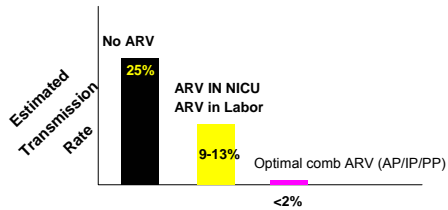


Reducing HIV Transmission with Suboptimal Regimens: The New York Cohort



Rationale

An intervention – ARV Prophylaxis



Wade, et al. 1998 NEJM 339:1409-14
Guy, et al. 1999 Lancet 354:795-802
Fiscus, et al. 2002 Ped Int Dis J 21:664-668
Moodley, et al. 2003 JID 167:725-735

P. Garcia

New Guidelines

Perinatal HIV Transmission Prevention

- 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. July 8, 2008; Public Health Service Task Force – Perinatal HIV Guidelines Working Group <http://AIDSinfo.nih.gov>
- Perinatal Antiretroviral Guidelines Updated. Amanda M. Cotter, MD; 11/20/07 HIV CareLink from Florida/Caribbean AETC www.FAETC.org/Newsletter

New Guidelines – **Key Ideas**

Perinatal Transmission Prevention

- Reconfirmed the **importance of ART** during pregnancy, delivery and post-delivery for the infant for optimal prevention.
- ART use in Pregnancy, **Dual Decision-Making**
 - 1) maternal health
 - 2) prevention of transmission to the infant
- **Combination ART regimens** are better than monotherapy
- Pre-conceptual counseling + recommend an effective, **non-teratogenic regimen**
- Maximal, **sustained viral replication suppression** is recommended pre-pregnancy

New Guidelines – Key Ideas
Perinatal Transmission Prevention

- In the management of the pregnant HIV-negative woman with an HIV-positive partner
 - 2nd HIV test in the 3rd trimester before 36 weeks
 - HIV RNA testing for suspected seroconversion
- Optimize pre-pregnancy and pre-partum care
 - ART regimens
 - Co-infection with Hep B or Hep C management
 - Improve pre-conceptual health
 - (MMWR Recommend Rep, 2006. 55(RR-6):1-23
 - www.cdc.gov/mmwr

Antepartum Management Issues

- Prior ARV exposure – use history and resistance testing results to guide ARV choice
- Co-infection with Hepatitis B
 - Chronic Hep B infection – 3 drug regimen with NRTI backbone of TDF + (3TC or FTC)
 - No interferon in pregnancy
 - Counsel mom re: hepatotoxicity signs + symptoms
 - Infants need HBIG and HBV vaccine <12 hours age
- Co-infection with Hepatitis C
 - No interferon or ribavirin in pregnancy
 - Use a 3 drug regimen regardless of viral load
 - Test infant by HCV RNA @ 2-6 months, Ab > 15 months

Antepartum Management Issues

- Monitoring of HIV+ Pregnant women
 - CD4 counts at 1st visit and every 3 months
 - HIV RNA at 1st visit, 2-6 weeks after starting/ changing ARV therapy
 - Monthly HIV RNA until undetectable, then every 2 months
 - Resistance testing prior to starting and w/ suboptimal suppression

Antepartum Management Issues

- No Nelfinavir, unless new data or no other choice
- Stopping ARVs (if Hyperemesis or Toxicity)
Stop them simultaneously
- Consider stopping NNRTI 1st then stop the others 7 days later

Intrapartum Management

- Perform a cesarean delivery for viral load >1000 copies/mL.
- Discuss Elective Cesarean Section – a choice regardless of viral load #
- For HIV-infected women with no ARVs during pregnancy; give intrapartum IV AZT plus 6 weeks of AZT for the infant are recommended.
- Addition of a single dose of NVP to an ongoing HAART regimen is **NOT** recommended for the mother or the infant.

Postpartum Complications

- Increased Maternal Risk for:
 - Postpartum Endometritis (p<0.001)
 - Require Blood Transfusion (p<0.02)
 - Develop Maternal Sepsis (p<0.001)
 - Be Treated for Pneumonia (p<0.001)
 - Maternal Death (p<0.001)

Louis et al OBGYN VOL. 110, NO. 2, PART 1, AUGUST 2007

PostPartum Complications

After controlling for potential confounders:

- **HIV-Infected Women were more likely to have one or more postpartum morbidities (OR 1.6, 95% confidence interval 1.2–2.2).**
- **CONCLUSION: Women w/ HIV infection Undergoing Cesarean delivery are at Increased Risk for Perioperative Morbidity and Maternal Mortality.**

• Louis et al OBGYN VOL. 110, NO. 2, PART 1, AUGUST 2007

Postpartum Management

Women who test (+) with a Rapid HIV test need

- Confirmatory testing
- Complete Evaluation
- ID Consultation
- Bio-Psycho-Social Interventions
- Referrals
- Breast Feeding Education

Postpartum Management

- Avoid Methergine for uterine atony if the mother was receiving EFV or a PI due to potential excessive adverse response.
- The decision to stop or continue ART In the mother depends on:
 - Symptoms
 - Stage of disease,
 - CD4 count nadir
 - Patient – Physician Discussion.

HIV Exposed Infant Care



New Guidelines Management of the Infant

- **Complex scenarios or possible toxicity in the infant; consult a pediatric HIV expert**
- **Sub-optimal Viral Load suppression**
Scheduled cesarean section
Vaginal delivery – VL > 10,000 or 30,000 = higher risk, but uncertain benefit of additional ARVs for the infant
- **Infants born to mothers receiving only intrapartum ARV medications**
At least 6 weeks of AZT, start ASAP
AZT for 6 weeks + single dose of NVP
AZT for 6 weeks + 1 week 3TC + 1 dose NVP
Triple ARV therapy

New Guidelines Management of the Infant

- **Infants born to mothers without antepartum or intrapartum ARV medications (consultation)**
AZT for 6 weeks postpartum starting at <12, <48 hours age (after 48 hours no benefit)
AZT for 6 weeks + 3TC for 1 week +NVP
Triple ARV therapy for 6 weeks
- **Infants born to mothers with ARV resistant virus**
Consult a Pediatric HIV specialist before delivery, with resistance data.
AZT for at least 6 weeks
Combination therapy based on resistance data of no data concerning benefit (multiple factors to consider)

An Important Old Guideline

- In the United States and other plentiful resource countries with excellent availability of formula;
- No Breastfeeding and No Breast milk helps Prevent Perinatal and Postnatal HIV Transmission.





Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings

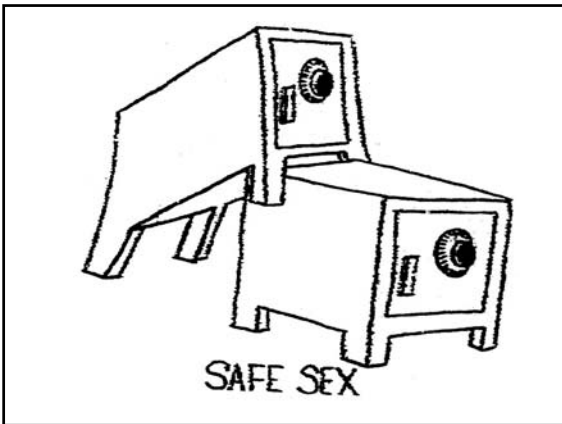
- HIV screening included in **routine** prenatal screening tests for all pregnant women.
- HIV screening after the patient is notified that testing will be performed unless the patient declines (**opt-out screening**).

Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings

- *Separate written consent for HIV testing should not be required; **General consent** for medical care should be considered sufficient to encompass consent for HIV testing.*
- ***Repeat screening in third trimester*** is recommended in certain jurisdictions with elevated rates of HIV infection

ACOG Recommendations

- **Opt-out** prenatal HIV testing
- **Repeat HIV testing in 3rd trimester** for women:
 - in areas with high HIV prevalence ($\geq 0.5\%$)
 - known to be at high risk for HIV-infection
 - who declined earlier HIV testing
- **Rapid HIV testing** for women in labor with undocumented HIV status
 - initiate ARV prophylaxis (with consent) for women with positive results without waiting for confirmatory test results



Rapid Human Immunodeficiency Virus-1
Testing To Prevent Perinatal HIV

Results:

- Sacred Heart Womens and Childrens Center Penasola, FI
- Time Period April 1, 2004 – March 31,2005
- 3552 Deliveries on Labor and Delivery
- 1,867 Rapid HIV Tests Done on L&D
- 641 Charts Reviewed

Helgott et al

Obstet and Gynecol 107(4) Supplement, April 2006, pp 2S-3S ACOG ACNM

Rapid HIV-1 Testing
To Prevent Perinatal HIV Transmission

Results:

1st Trimester HIV Test

79%	Tested
7.0%	Not Tested
4.2%	Declined
9.5%	No Data on Chart

Helgott et al

Obstet and Gynecol 107(4) Supplement, April 2006, pp 2S-3S ACOG ACNM

Rapid HIV-1 Testing
To Prevent Perinatal HIV Transmission

Results:

Third Trimester Tests

7.8%	Tested
61.8%	Not Tested
2.5%	Declined
27.9%	No Data on Chart

Rapid Human Immunodeficiency Virus-1
Testing To Prevent Perinatal HIV

Results:

Reasons for Rapid HIV Testing @ Delivery

- No 3rd Δ Test 72.1%
- No PNC 3.3%
- Declined Test Previously 4.2%
- No PN Results 11.5%
- Retested @ Delivery 4.7%
- NEVER OFFERED TEST 2.0%

Rapid Human Immunodeficiency Virus-1
Testing To Prevent Perinatal HIV

Results:

- 2 Patients Tested Positive
- Both Children Seronegative
- 2 False Positives, Western Blots Negative

Helgott et al
Obstet and Gynecol 107(4) Supplement, April 2006, pp 2S-3S ACOG ACNM

Rapid Human Immunodeficiency Virus-1
Testing To Prevent Perinatal HIV

Conclusion:

- Rapid HIV Testing on L&D Can Be Successfully Implemented
- Problems w/ Conveying Prenatal Information to Delivery Site
- Despite the Law NOT ALL Women are Offered HIV Testing

Helgott et al
Obstet and Gynecol 107(4) Supplement, April 2006, pp 2S-3S ACOG ACNM

Rapid Human Immunodeficiency Virus-1 Testing To Prevent Perinatal HIV

Conclusion:

- Rapid HIV Testing on L&D is a Cost Effective Method to Prevent Perinatal HIV
- Identifying Two (+) Mothers Potentially Saved \$346,000 by Preventing 2 Cases Perinatal HIV

Helgott et al
Obstet and Gynecol 107(4) Supplement, April 2006, pp 2S-3S ACOG ACNM



Resources

- Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>
- UCSF National HIV/Aids Clinicians Consultation Center
<http://www.nccc.ucsf.edu/>
- Helgott AW, et al Rapid HIV-1 Testing to Prevent Perinatal HIV. *Obstet and Gynecol* 107(4) Supplement, April 2006, pp 2S-3S
- Louis et al *Perioperative Morbidity in HIV-Infected Women* OBGYN VOL. 110, NO. 2, PART 1, AUGUST 2007

Obstetrical Tools and Guides

- CareLink F/C AETC – **Updates to Interventions** to Reduce Perinatal HIV Transmission – A. Cotter, MD
www.FAETC.org/Newsletter_11/20/07
- Use of ARVs in Pregnancy – Recommendations for Use of ARV Drugs in Pregnant HIV-Infected for Mental Health and Interventions to Reduce Perinatal HIV Transmission in the US. Table 2 - **Preclinical and Clinical Data** - from PHS Task Force, July 2008 <http://AIDSinfo.nih.gov>
- Use of ARVs in Pregnancy – Recommendations for Use of ARV Drugs in Pregnant HIV-Infected for Mental Health and Interventions to Reduce Perinatal HIV Transmission in the US. Table 3 - **Pharmacokinetic and Toxicity Data** - from PHS Task Force, July 2008 <http://AIDSinfo.nih.gov>

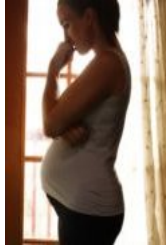


Obstetrical Tools and Guides

- Targeted Outreach for Pregnant Women Act Program (**TOPWA**), Florida
[1/http://www.doh.state.fl.us/disease_ctrl/aids/updates/facts/BW04Women.pdf](http://www.doh.state.fl.us/disease_ctrl/aids/updates/facts/BW04Women.pdf)
- **Informational Handouts** for Pregnant Women – www.aidsinfonet.org
- Mother to Child Transmission – A. Cotter, MD and J. Potter, PhD, www.FAETC.org – see Resources, Clinical Care Manuel
- **Rapid HIV Testing in L & D**
http://www.cdc.gov/hiv/rapid_testing/
<http://www.cdc.gov/hiv/projects/perinatal/>

Obstetrical Tools / Handouts

- Recommendations to Improve Preconception Health www.cdc.gov/mmwr MMWR Recomm Rep, 2006. 55(RR-6):1-23.
- Florida Law: **STD Testing in Pregnancy** <http://www.doh.state.fl.us> Florida Law # 64D-3.042 STD Testing Related to Pregnancy
- The ARV Pregnancy Registry http://www.apregistry.com/forms/interim_report.pdf
- Practical Guide to Management of GYN Problems in HIV-Infected Women. J. Potter, PhD et al. www.FAETC.org/Newsletter HIV CareLink 2/16/07





Collaborative Models

- Necessary Services for Women
- Targeted Outreach Pregnant Women Act
- Rainbow Center, Jacksonville, FL
- Univ. of Miami, Miami, FL
- Opportunity for Collaboration Red Ribbon Alliance, Tallahassee FL



**Necessary Services
for HIV-Infected Women**

- **Legal Aid Services**
- **Support Groups** for Peer support
- Consumer Advisory Board/Group
- **Access to clinical trials** – HIV research program
- **Medication Adherence Program** and Health Education
- **Risk Reduction** evaluation/counseling, Behavior Modification & **sex education**

**Necessary Services
for HIV-Infected Women**

- **Specialty and Primary Medical Care for Women**
- **Mental Health Evaluation & Counseling**
- **Nutritional assessment:** BIAs and Counseling
- Nursing **Case Management**
- Social Work Case Management
- **Testing and Counseling:** community sites
- **Substance Abuse** Evaluation and Referral for Treatment

**Necessary Services
for HIV-Infected Women**

- **OB / GYN Care for women** – cancer screening, contraceptive counseling, obstetrical care, post-partum follow-up, prenatal counseling
- **Pre-conceptual Counseling** – advice concerning improving pre-conceptual health, discussion of interventions to prevent perinatal HIV transmission
- **Prenatal Consultation with Pediatric Services:** primary pediatrician and specialty service
- **Emergency Services:** access and care



Targeted Outreach for Pregnant Women Act (TOPWA)

- 1999 Program began in 12 Florida Counties
- 1999 – 2005
 - Screened >131,000 women for eligibility
 - Enrolled ~ 20,000 HIV+, high risk women
 - Enrolled women ~83% minorities
 - 42% not in prenatal care
 - Conducted new HIV testing
 - >15,000 HIV tests done
 - Seropositivity rate of 1.8% (0-3.2%)
 - Testing in local county jails (3)

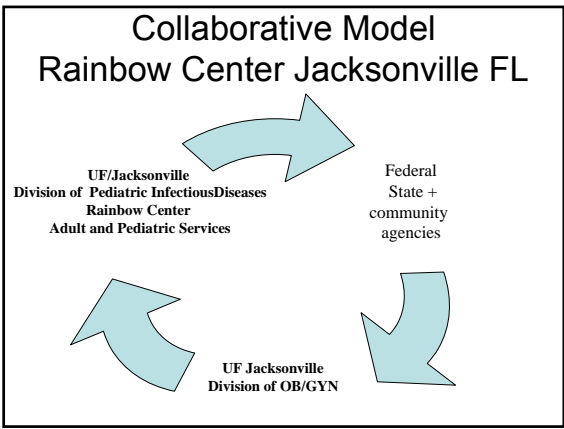
TOPWA

Reasons for No/Inadequate Prenatal Care

• Concern about testing for drugs (0.7%)	• Couldn't find a doctor (3.2%)
• Concern about testing for HIV (0.5%)	• No one to care for my children (2.7%)
• Couldn't get an appointment (5.9%)	• Didn't know I was pregnant (39.7%)
• No money or insurance (35.1%)	• Refused answer (2.9%)
• No Transportation (19%)	• Other (11.9%)
	• Too busy (3.5%)

1/http://www.doh.state.fl.us/disease_ctrl/aids/updates/facts/BW04Women.pdf

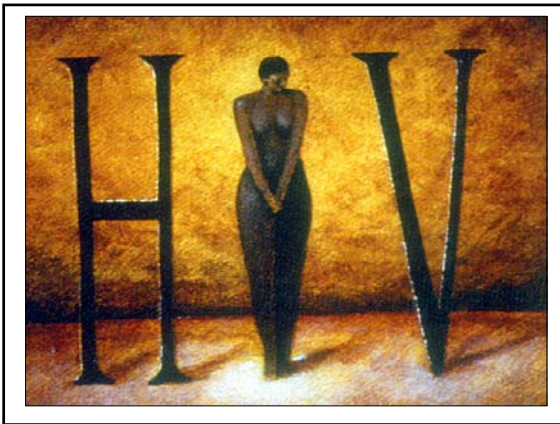




- Partners in Care**
Rainbow Center Jacksonville, FL
- **OB/GYN Division:**
 - HIV +Women seen get PAPS, GYN Care including Colpos and LEEPs
 - HIV+ Women receive counseling by Psychologist and Providers
 - Pregnant HIV+ women have access to social case managers and the dietitian at Rainbow. Perinatal visits are offered to all HIV pregnant mothers
 - **ER:** Trainings given to identify and refer high risk patients
 - **Community Based Organizations:** Training given, continuity of care is emphasized.

Partners in Care
Rainbow Center Jacksonville, FL

- **Jail Link Program**
- **Ryan White** Part A,B,C,D Funded Program
- **Education and Outreach** (TOPWA Funds)
- **TOPWA** Program funded by the HIV/AIDS Bureau and managed by Rainbow provide outreach and help increase access to care
- **Mother/baby Connection:** Provides Peer support group as well as education/counseling
- **Children's Medical Services** Funds

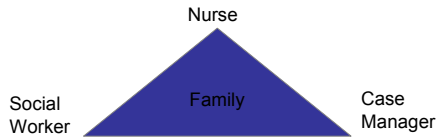


Collaborative Model
University of Miami - Dept. of OB/GYN

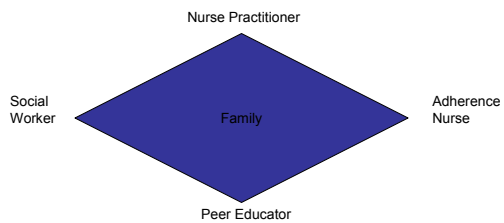
- Began in the 1980s
- Evolved over time to meet the needs of the patients / family
- Increasing number of patients and Increasing number of services and collaborations
- Still evolving today

Needs in 1988

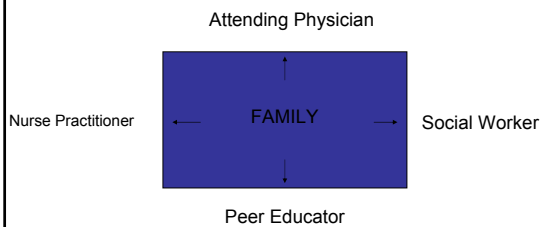
- Very sick child and mother :
“intensive” psycho-social case management model
- Treatment very limited:
mostly psychosocial support and concrete needs



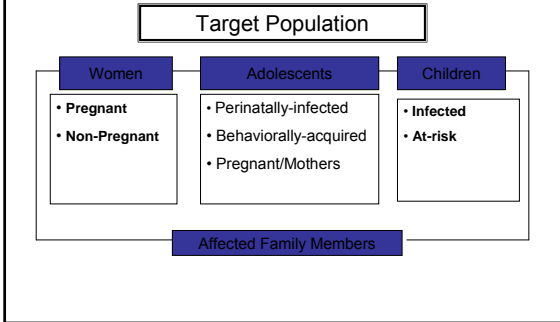
Family Centered Model of Comprehensive Care



The New Face of HIV/AIDS



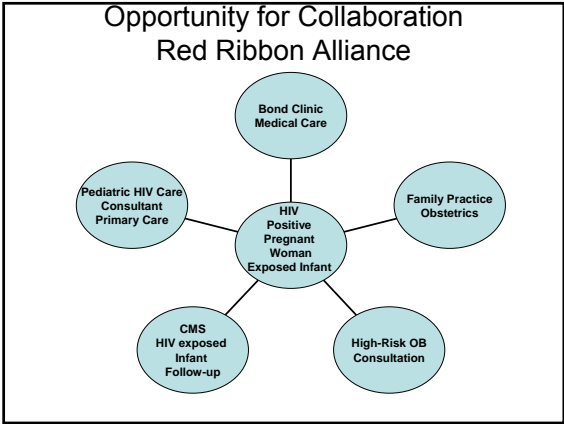
Miami Family Care Program Model



Miami Family Care Program Services

Specialty Care: In & Outpatient	Psychiatry & Behavioral Health	Developmental Services	Clinical Research	Referral Services
<ul style="list-style-type: none"> • Obstetrics • Gynecology • Pediatric & adult/adolescent immunology • Nutrition • Adherence counseling • STD & HIV screening, counseling & testing • Medical case management • Outreach & case finding 	<ul style="list-style-type: none"> • Psychological • Psychiatric • Crisis intervention • Adherence interventions • Substance abuse • Support groups • Psychosocial counseling 	<ul style="list-style-type: none"> • Developmental assessment & interventions • Speech, language, occupational & physical therapy • School intervention • Parenting 	<ul style="list-style-type: none"> • PACTG – Pediatrics • PACTG-OB • Adolescent Trials Network • Mother Infant Rapid Intervention at Delivery-MIRIAD • Other clinical & behavioral research 	<ul style="list-style-type: none"> • Primary care in community • Pediatric Mobile Van • Dental • Ophthalmology • Other sub-specialties • RW Title 1 agencies • WIC • Client advocacy • CHRE





- ### Opportunity for Collaboration Red Ribbon Alliance
- **Enhance Communication between**
 HIV Medical Service – Bond Clinic
 Family Practice Obstetrical Service
 Hospital L & D Service – TM Hospital
 Pediatric HIV Consultant – Children’s Med Services
 Primary Care Pediatrics – private practitioners
 - **Community Collaborators**
 Big Ben Cares – Community Board
 Case Management Services
 Psychiatric and Behavioral Services
 Community-based Counseling and Testing Programs
 Substance Abuse Programs
 WIC
 Jail Link Program

- ### Opportunity for Collaboration Red Ribbon Alliance
- **Florida / Caribbean AETC Program Development**
 Perinatal HIV Transmission Prevention
 Rapid HIV Testing in L&D – technical support
 Improving Prepregnancy Health in HIV+ Women
 Care and Follow-up of HIV-Exposed Children
 Obstetrical Care of the HIV-Infected Woman
 Dental Care for HIV+ Individuals
 - **Ryan White Funded Programs**
 Subspecialty Care Services
 ADAPT pharmacy and adherence services
 Community Outreach and Case Finding

Questions / Discussion



Resources

- ❑ **National Model Protocol**
www.cdc.gov/hiv/projects/perinatal/
- ❑ **USPHS Treatment Guidelines**
www.aidsinfo.nih.gov
- ❑ **FXBC at UMDNJ** www.WomenChildrenHIV.org
- ❑ **ACOG** www.acog.org
- ❑ **AETC** <http://hab.hrsa.gov/educating.htm>

Pediatric Tools and Handouts

- **HIV exposed infants standard of care visit schedule** (handout)
- **Nursery Admission Orders** for HIV exposed infants (handout)
- **ARV medication dosing** for infants
www.FAETC.org (resources – treatment guides – Pocket Reference Cards – ARV pediatric guide 3/08)
- **Immunization Schedule** for infants, 2008
www.cdc.gov/vaccines/recs/schedules
- **Explanation of Testing** of exposed infants, for mothers/parents/guardians (handout)
- **Prenatal Consultation** with the HIV-Infected Pregnant Woman (handout)

Pediatric Tools and Handouts

- Diagnosis of HIV-1 Infection in Children Younger than 18 Months in the US. Read JS, and Comm. on Pediatric AIDS
Pediatrics 2007;120(6);e1547-1562.
<http://www.pediatrics.org/cgi/content/full/120/6/e1547>
- Evaluation and Treatment of the HIV-1- Exposed Infant.
King SM, and Comm. on Pediatric AIDS
Pediatrics 2004;114;497-505.
<http://www.pediatrics.org/cgi/content/full/114/2/497>

Medical Care for HIV-Infected Women Tools and Handouts

- Recommendations to Improve Preconception Health www.cdc.gov/mmwr MMWR Recomm Rep, 2006. 55(RR-6):1-23.
- Contraceptive Counseling
- Safer Sex Practices
- Pre-conceptual Consultation – reproductive options and recommendations
- Post-partum Follow-up of HIV-Infected Women