HIV AND PREGNANCY IN ALABAMA
2015 Review of Current Guidelines and State Resources

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1. HIV in Pregnancy Fact Sheet for the Public

- All pregnant women should be screened for HIV as early as possible during each pregnancy with an opt-out testing approach. 18% of people with HIV infection in the US are not aware of their infection.

- The earlier HIV is diagnosed during pregnancy the better so that medication can be started to help reduce the risk of the woman passing HIV to the baby.

- Women with HIV infection are more and more interested in having children over the past decade. In 2006, 8700 women with HIV infection gave birth.

- Women with HIV who take antiretroviral medication during pregnancy as recommended can reduce the risk of transmitting HIV to their babies to less than 1%.

- Since the mid-1990s, HIV testing and preventive interventions have resulted in more than a 90% decline in the number of children perinatally infected with HIV in the United States.

- Fortunately, there are fewer than 200 new infections of HIV passed from mom to infant each year in the United States. The risk of transmitted infection is much higher when women do not have regular prenatal care.

- Women in the US with HIV are advised to bottlefeed their infants instead of breastfeeding since the HIV virus can be passed through breastfeeding.

- Anyone with questions about HIV testing or prior test results should talk with their healthcare provider. Since 2006, the CDC has recommended for all adults to undergo HIV testing as a part of their routine health care (at least once). Women and men who are at high risk of acquiring HIV should be tested each year.

2. HIV Epidemiology in the US and in Alabama

Reference: HIV Surveillance in Alabama –2012 ADPH Annual Report by the HIV Surveillance Branch (revised 6/5/14) and CDC (national statistics)
http://www.adph.org/aids/assets/Finalized_2012HIVSurveillance_R_2.pdf

In the US, there are approximately 1.1 million people who have HIV infection and there are 50,000 new infections each year. Forty-five percent of new HIV infections in 2010 were among Americans who resided in the South. At the end of 2012, there were 11,815 HIV-infected individuals living in Alabama and 661 had newly detected infections while 4838 (41%) carried a diagnosis of AIDS. Twenty-one percent of incident HIV infections (n=138) and 28% of prevalent HIV infections (n=3312) were among women. Although the entire state has been impacted by this infection, the majority of cases were reported in 3 counties: Jefferson (28%), Montgomery (19%) and Mobile (15%). While case-rates are decreasing among heterosexuals, they continue to increase among men who have sex with men (MSM) and many of these men report having had sex with both men and women. The number of HIV/AIDS deaths has decreased since the availability of effective combination antiviral therapy for HIV, yet the number of people living with HIV infection has continued to increase.

Nationwide, about 18% of people with HIV are not aware of their infection, so in Alabama in 2012, there were approximately 14,426 individuals with HIV infection. The cascade of care is a measure of how many people with HIV are engaged in healthcare, including how many are taking medicines for HIV and how many have reached the goal of suppressed HIV viral load. In Alabama, of the approximately 14,000 people with infection, only about 5000 are retained in care and less than 4000 people have a suppressed HIV viral load (defined as viral load <200 copies/mL). There is more work to be done at each step of the cascade in order to improve HIV care over the long term.

In the US, there are over 8700 women each year with HIV who become pregnant. As of 2012, there were 153 children < 13 years old living with HIV infection in Alabama.

3. Summary of 2014 HIV Pregnancy Guidelines (links to online resources are provided at the end of the document)

Rating of Recommendations: A = Strong; B = Moderate; C = Optional
Rating of Evidence: I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

A) Preconception Counseling

Panel's Recommendations

- Discuss childbearing intentions with all women of childbearing age on an ongoing basis throughout the course of their care (AIII).
- Include information about effective and appropriate contraceptive methods to reduce the likelihood of unintended pregnancy (AI).

- During preconception counseling, include information on safer sexual practices and elimination of alcohol, illicit drugs, and smoking, which are important for the health of all women as well as for fetal/infant health, should pregnancy occur (AII).
- All HIV-infected women contemplating pregnancy should be on a maximally suppressive antiretroviral regimen (AII).
- When selecting or evaluating combination antiretroviral therapy (ART) for HIV-infected women of childbearing age, consider a regimen's effectiveness, a woman's hepatitis B virus disease status, teratogenic potential of the drugs in the ART regimen, should pregnancy occur, and possible adverse outcomes for the mother and fetus (AII).

B) Antiretroviral Use in Pregnancy

Panel's Recommendations

- **Given the complexity of choosing an antiviral regimen for HIV-infected pregnant women and changes in recommendations as new information becomes available, clinical consultation with an expert in HIV management is strongly recommended.**
- Initial evaluation of HIV-infected pregnant women should include assessment of HIV disease status and recommendations regarding initiation of combination antiretroviral therapy (ART) or the need for any modification if currently receiving ART (AIII).
- All pregnant HIV-infected women should receive ART to prevent perinatal transmission regardless of plasma HIV RNA copy number or CD4 T lymphocyte count (AI).
- Combined antepartum, intrapartum, and infant antiretroviral (ARV) prophylaxis is recommended because ARV drugs reduce perinatal transmission by several mechanisms, including lowering maternal antepartum viral load and providing infant pre- and post-exposure prophylaxis (AI).
- The known benefits and potential risks of ARV use during pregnancy should be discussed with all HIV-infected women (AIII).
- In counseling patients, the importance of adherence to their ARV regimens should be emphasized (AII).
- ARV drug-resistance studies should be performed before starting or modifying ARV drug regimens in women whose HIV RNA levels are above the threshold for resistance testing (i.e., >500 to 1,000 copies/mL) (AIII).
- When HIV is diagnosed later in pregnancy, ART should be initiated promptly without waiting for results of resistance testing (BIII).
- Coordination of services among prenatal care providers, primary care and HIV specialty care providers, and when appropriate, mental health and drug abuse treatment services, and public assistance programs, is essential to ensure that infected women adhere to their ARV drug regimens (AIII).
- Multiple factors must be considered when choosing a regimen for a pregnant woman including comorbidities, convenience, adverse effects, drug interactions,

resistance testing results, pharmacokinetics (PK), and experience with use in pregnancy. (AIII).

- PK changes in pregnancy may lead to lower plasma levels of drugs and necessitate increased dosages, more frequent dosing, or boosting, especially of protease inhibitors (AII).

C) Clinical and Laboratory Monitoring during Pregnancy

Panel's Recommendations

- Plasma HIV RNA levels should be monitored at the initial visit (AI); 2 to 4 weeks after initiating or changing antiretroviral drug regimens (BI); monthly until RNA levels are undetectable (BIII); and then at least every 3 months during pregnancy (BIII). HIV RNA levels also should be assessed at approximately 34 to 36 weeks' gestation to inform decisions about mode of delivery (AIII).
- CD4 T lymphocyte (CD4) cell count should be monitored at the initial antenatal visit (AI) and at least every 3 months during pregnancy (BIII).
- Genotypic ARV drug-resistance testing should be performed at baseline in all HIV-infected pregnant women with HIV RNA levels above the threshold for resistance testing (that is, >500 to 1,000 copies/mL), whether they are ARV-naive or currently on therapy (AIII).
- Repeat genotypic testing is indicated following initiation of an ARV regimen in women who have suboptimal viral suppression or who have persistent viral rebound to detectable levels after prior viral suppression on an ARV regimen (AII).
- Monitoring for complications of ARV drugs during pregnancy should be based on what is known about the adverse effects of the drugs a woman is receiving (AIII).
- HIV-infected women taking ART during pregnancy should undergo standard glucose screening at 24 to 28 weeks' gestation (AIII).
- Early ultrasound is recommended to confirm gestational age and, if scheduled cesarean delivery is necessary, to guide timing of the procedure (AII).

D) Intrapartum Care

Panel's Recommendations

- Women should continue their antepartum combination antiretroviral (ARV) drug regimen on schedule as much as possible during labor and before scheduled cesarean delivery (AIII).
- Intravenous (IV) zidovudine should be administered to HIV-infected women with HIV RNA >1,000 copies/mL (or unknown HIV RNA) near delivery (AI). During labor, zidovudine is administered intravenously in a 1-hour initial dose of 2 mg/kg body weight, followed by a continuous infusion of 1 mg/kg body weight/hour until delivery. IV ZDV infusions should begin 3 hours prior to cesarean delivery.
- IV zidovudine is not required for HIV-infected women receiving combination ARV regimens who have HIV RNA ≤1,000 copies/ mL consistently during late

pregnancy and near delivery and for whom there are no concerns regarding adherence to the regimen (BII).

- Viral loads should be consistently suppressed when intrapartum IV zidovudine is not used. However, regardless of viral load, the clinician may elect to use intrapartum IV zidovudine based on clinical judgment.
- For women who have suboptimal viral suppression near delivery (i.e., HIV RNA >1,000 copies/mL), scheduled cesarean delivery is recommended (AI).
- Women whose HIV status is unknown who present in labor should undergo rapid HIV antibody testing (AII). If the rapid test results are positive, a confirmatory maternal HIV test should be done as soon as possible and maternal (IV zidovudine)/infant (combination ARV prophylaxis) ARV drugs should be initiated pending results of the confirmatory test (AII). If the confirmatory maternal HIV test is positive, infant ARV drugs should be continued for 6 weeks (AI); if the confirmatory HIV test is negative, the infant ARV drugs should be stopped.

E) Postpartum Care

Panel's Recommendations

- Decisions regarding continuing combination antiretroviral therapy (ART) after delivery should be made in consultation with the woman and her HIV provider, ideally before delivery (AIII). ART is currently recommended for all HIV-infected individuals to reduce the risk of disease progression and to prevent HIV sexual transmission, although the strength and evidence for this recommendation varies by pre-treatment CD4 T lymphocyte (CD4) count.
- For women continuing ART postpartum, arrangements for new or continued supportive services should be made before hospital discharge because the immediate postpartum period poses unique challenges to adherence (AII).
- Contraceptive counseling should be a critical aspect of postpartum care (AIII).
- [$] Women with a positive rapid HIV antibody test during labor require immediate linkage to HIV care and comprehensive follow-up, including confirmation of HIV infection. If infection is confirmed, a full health assessment is warranted, including evaluation for associated medical conditions, counseling related to newly diagnosed HIV infection, and assessment of need for ART and opportunistic infection prophylaxis (AII).
- Breastfeeding is not recommended for HIV-infected women in the United States, including those receiving ART (AII).

F) Pediatric Care – Infant ARV Prophylaxis

Panel's Recommendations

- The 6-week neonatal component of the zidovudine chemoprophylaxis regimen is generally recommended for all HIV-exposed neonates to reduce perinatal transmission of HIV (AI). A 4-week neonatal chemoprophylaxis regimen can be considered when the mother has received standard combination antiretroviral

therapy (cART) during pregnancy with consistent viral suppression and there are no concerns related to maternal adherence (BII).

- Zidovudine, at gestational age-appropriate doses, should be initiated as close to the time of birth as possible, preferably within 6 to 12 hours of delivery (AII).
- Women whose HIV status is unknown who present in labor should undergo rapid HIV antibody testing (AII). If the rapid test results are positive, a confirmatory maternal HIV test should be done as soon as possible and maternal (IV zidovudine)/infant (combination ARV prophylaxis) ARV drugs should be initiated pending results of the confirmatory test (AII). If the confirmatory maternal HIV test is positive, infant ARV drugs should be continued for 6 weeks (AI); if the confirmatory HIV test is negative, the infant ARV drugs should be stopped.
- Infants born to HIV-infected women who have not received combination ART during pregnancy should receive prophylaxis with zidovudine given for 6 weeks combined with three doses of nevirapine in the first week of life (i.e., at birth, 48 hours later, and 96 hours after the second dose), begun as soon after birth as possible (AI).
- In other scenarios, the decision to combine other drugs with the 6-week zidovudine regimen should be made in consultation with a pediatric HIV specialist, preferably before delivery, and should be accompanied by maternal counseling on the potential risks and benefits of this approach (BIII).
- In the United States, the use of ARV drugs other than zidovudine and nevirapine cannot be recommended in premature infants as prophylaxis to prevent transmission because of lack of dosing and safety data (BIII).

G) Pediatric Care – Initial Postnatal Management of the HIV Exposed Neonate

Panel's Recommendations

- A complete blood count and differential should be performed on newborns as a baseline evaluation (BIII).
- If hematologic abnormalities are identified in infants receiving prophylaxis, decisions on whether to continue infant antiretroviral (ARV) prophylaxis need to be individualized. Consultation with an expert in pediatric HIV infection is advised if early discontinuation of prophylaxis is considered (CIII).
- Decisions about the timing of subsequent monitoring of hematologic parameters in infants depend on baseline hematologic values, gestational age at birth, clinical condition of the infants, the zidovudine dose being administered, receipt of other ARV drugs and concomitant medications, and maternal antepartum therapy (CIII).
- A recheck of hemoglobin and neutrophil counts is recommended 4 weeks after initiation of prophylaxis for infants who receive combination zidovudine/lamivudine-containing ARV prophylaxis regimens (AI).
- Virologic tests are required to diagnose HIV infection in infants aged <18 months and should be performed within the first 14 to 21 days of life and at age 1 to 2 months and age 4 to 6 months (AII).

- To prevent Pneumocystis jirovecii pneumonia (PCP), all infants born to HIV-infected women should begin PCP prophylaxis at ages 4 to 6 weeks, after completing their ARV prophylaxis regimen, unless there is adequate test information to presumptively exclude HIV infection (AII).
- Health care providers should routinely inquire about premastication, instruct HIV-infected caregivers to avoid this practice, and advise on safer feeding options (AII).

Recommended Neonatal Dosing for Prevention of Perinatal Transmission of HIV

All HIV-Exposed Infants (initiated as soon after delivery as possible)		
Gestational age	Zidovudine (ZDV) Dosing	Duration
≥35 weeks gestation at birth:	4 mg/kg/dose PO twice daily, started as soon after birth as possible and preferably within 6–12 hours of delivery (or, if unable to tolerate oral agents, 3 mg/kg/dose IV, beginning within 6–12 hours of delivery, then every 12 hours)	Birth through 4-6 weeks
≥30 to <35 weeks gestation at birth:	2 mg/kg/dose PO (or 1.5 mg/kg/dose IV), started as soon after birth as possible, preferably within 6–12 hours of delivery, then every 12 hours, advanced to 3 mg/kg/dose PO (or 2.3 mg/kg/dose IV) every 12 hours at age 15 days	Birth through 6 weeks
<30 weeks gestation at birth:	2 mg/kg body weight/dose PO (or 1.5 mg/kg/dose IV) started as soon after birth as possible, preferably within 6–12 hours of delivery, then every 12 hours, advanced to 3 mg/kg/dose PO (or 2.3 mg/kg/dose IV) every 12 hours after age 4 weeks	Birth through 6 weeks
Additional Antiretroviral Prophylaxis Agents for HIV-Exposed Infants of Women who Received No Antepartum Antiretroviral Prophylaxis (initiated as soon after delivery as possible)		
In addition to ZDV as shown above, administer NVP	Birth weight 1.5–2 kg: 8 mg/dose PO Birth weight >2 kg: 12 mg/dose PO	3 doses in the first week of life • 1st dose within 48 hrs of birth (birth–48 hrs) • 2nd dose 48 hrs after 1st • 3rd dose 96 hrs after 2nd

A 6-week course of neonatal zidovudine is generally recommended.
A 4-week neonatal zidovudine chemoprophylaxis regimen may be considered when the mother has received standard ART during pregnancy with consistent viral suppression and there are no concerns related to maternal adherence.

4. Alabama Resources for HIV Care in Pregnancy and Pediatric HIV

UAB Department of OB/GYN Division of Maternal-Fetal Medicine
Birmingham, Alabama

Alan Tita, MD or other MFM Physician on Call
UAB Obstetrical Complications Clinic
(205) 934-MIST
(205) 934-2565

Mickey Parks, CRNP
Obstetrical care provider for HIV Infected Women
(205) 934-2170

HIV care during pregnancy:
Jodie Dionne-Odom, MD
1917 Medical Clinic
908 20th Street South
Division of Infectious Diseases
University of Alabama at Birmingham
(205) 934 1917

UAB Family Clinic at Children's of Alabama
Marsha Sturdevant, MD, Director
1600 5th Avenue South
Birmingham, AL 35233
(205) 939-9400

For HIV Exposed Infants:
Suzanne Cantley, CRNP
(205) 939-9400

For HIV Infected Infants and children:
Cecelia Hutto, MD or Pediatric Infectious Diseases Physician on call
(205) 934-2441

HIV Clinics in Alabama outside of Birmingham (in alphabetical order by location)

Health Services Center, Inc.
Barbara J. Hanna, MD, Clinical Director
608 Martin Luther king drive
Anniston, AL 36201
(256) 832-0100
(Serves fourteen county area of East Alabama)

Unity Wellness of East Alabama Medical Center
Marilyn Swyers, Executive Director
665 Opelika Road
Auburn, AL 36830
(334) 887-5244
1 (800) 799-4967

Davis Clinic, AIDS Action Coalition
Nicholas Carlisle, JD, Executive Director
AIDS Action Coalition
600 St Clair Ave
Bldg 6
Huntsville, AL 35801
(256) 536-4700

Franklin Memorial Primary Health Center Part C Clinic
1303 Dr. Martin Luther King, Jr Ave.
Mobile, AL
(251) 432-4117

Mobile County Health Department Part C Clinic
251 N Bayou St
Mobile, AL 36603
(251) 690-8158

University of South Alabama Family Specialty Clinic
Theresa Miller, PA
1504 Springhill Avenue, Fifth floor
Mobile, Alabama 36604
(251) 434-3485
(Serves Mobile County & Baldwin County)

Montgomery AIDS Outreach
Dr. Laurie Dill
2900 McGehee Road
Montgomery, Alabama 36111
(334) 280-3349 Montgomery (Copeland Care Clinic)
(334) 673-0494 MAO-Dothan
1 (800) 510-4704
(Serves Montgomery with rural clinics in Clayton, Georgiana, Troy, Tuskegee, Pineapple, Selma and a full-time clinic in Dothan)

Montgomery Internal Medicine Residency Program
Wick Many, MD
UAB School of Medicine
2055 East South Boulevard, Suite 202
Montgomery, AL
(334) 284-5211
1 (888) 467-0765

Selma AIR (Satellite Clinic of MAO)
Mel Prince, Executive Director
1432 Broad Street
Selma, AL 36701
(334) 872-6795

Whatley Health Services, Inc. Hope Clinic
Marquetta Campbell, Director
2731 Martin Luther King Boulevard
Tuscaloosa, AL 35401
(205) 349-3250

5. Additional Resources

a. Online Resources

The management of HIV in pregnancy is a rapidly changing field and up-to-date recommendations are available on the following websites:

1. National Institutes of Health – AIDS INFO
   http://aidsinfo.nih.gov

   a. HIV Pregnancy Treatment Guidelines (3/28/14 update)
      http://aidsinfo.nih.gov/contentfiles/lvguidelines/perinatalgl.pdf

   b. Pediatric HIV Treatment Guidelines (2/12/14 Update)
      http://aidsinfo.nih.gov/guidelines/html/2/pediatric-treatment-guidelines/0/

   c. Adult HIV Treatment Guidelines (5/1/14 update)
      http://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/0/

2. Centers for Disease Control (CDC)

   a. www.cdc.gov/hiv/ – main website on HIV with resources for the general public, clinicians and public health professionals.

   b. http://www.cdc.gov/hiv/risk/gender/pregnantwomen/ - website with information specific to HIV in pregnancy including fact sheets, community interventions and national epidemiology.

3. American Congress of Obstetricians and Gynecologists (ACOG)

   a. http://www.acog.org/About-ACOG/ACOG-Departments/HIV - HIV specific ACOG webpage which includes resources for HIV screening and training

4. Alabama Department of Public Health
   Statewide contacts and local resources for a variety of public health issues, including HIV.

   a. www.adph.org – main website

   b. www.adph.org/aids/ - website for the Division of HIV/AIDS Prevention and Control. It includes information about Alabama AIDS Drug Assistance Program (ADAP), an STD/HIV Report Card and up to date epidemiology.

b. Resources Available by Telephone

1. National Perinatal HIV Consultation Service (UCSF): 1-888-448-8765
   A federally funded service providing free clinical consultation for difficult cases to providers caring for HIV-infected pregnant women and their infants, and can provide referral to local or regional pediatric HIV specialists.

2. Alabama Department of Public Health HIV/AIDS Hotline: 1-800-228-0469

3. AIDS Alabama Confidential State Helpline: 1-800-592-2437

4. Alabama Coalition Against Domestic Violence: (334) 832-4842 (office)
   a. Statewide Hotline 24/7: 1-800-650-6522

Research opportunities for HIV infected women and their infants:

UAB 1917 Clinic Clinical Trials Unit
http://www.uab.edu/medicine/1917clinic/clinical-trials-aboutus-sidebar
Karen G. Savage, RN, BSN, CCRC
Research Manager
908 20th ST. South CCB 160
Birmingham, Al 35294-2050
Ph: 205-975-7925
Fax: 205-975-8273
Email: kgsavage@uab.edu

The Pediatric HIV/AIDS Cohort Studies (PHACS) established in 2005:
https://phacsstudy.org/About-Us/For-Non-Researchers
UAB Pediatrics and Children's of Alabama
Marilyn Crain MD, MPH
Paige Hickman, CRNP, Study Coordinator
205 996-7831

The SMARTT study is designed to answer questions of long term safety of antiretroviral (ART) treatment given in pregnancy and in the neonatal period. Pregnant women with HIV infection may enroll during the 23rd week of pregnancy. Children are evaluated as newborns and then once yearly in order to document any long-term effects of exposure to preventive HIV treatment. Participants receive stipends for their time.