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## Obstetrics Guidelines

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### **SUBJECT: CARE OF THE HIV INFECTED PREGNANT WOMAN**

#### **I. Guidelines for Workup of HIV Positive Women**

- A. Initial Laboratory Evaluation of Newly Diagnosed HIV Infected Pregnant Women (at time of referral):  
All tests are ordered by the patient's primary provider after which the patient is referred to the FCID/OB Center, Outpatient Care Center 1855 W. Taylor Street, Room 3D.
1. Confirmatory HIV test (ELISA) on different specimen than original
  2. T-cell subsets (i.e. CD 4 count and percentage)
  3. Standard quantitative HIV viral RNA PCR (i.e. viral load)
  4. HIV genotypic resistance profile
  5. Hepatitis A, B and C serology including Hepatitis B surface antibody to assess for immunity
  6. Cytomegalovirus serology (IgG)
  7. Toxoplasma serology (IgG)
  8. CBC with differential
  9. Electrolytes
  10. Renal function studies (BUN/creatinine)
  11. Liver function studies (minimum: transaminases)
  12. Fasting glucose
  13. Lipid profile
  14. Routine prenatal labs and cultures
  15. PPD and anergy panel if not done in the past year
  16. Urine toxicology screen if indicated
  17. Pap smear screening
  18. G6PDH deficiency screening

#### **II. Recommendations Regarding Antepartum Vaccinations**

- A. Vaccinate against the following
1. Hepatitis B if not already immune
  2. H. influenza
  3. Pneumococcus
  4. Influenza during the fall flu season (October through February)
  5. Rubella Vaccination post-partum as needed (Refer to Immunizations in Pregnancy Guidelines, I 1.15)
  6. Tetanus toxoid if not received in the past 10 years

#### **III. Antepartum Management of the HIV Positive Woman**

In addition to routine obstetrical care:

1. Monthly viral loads until non-detectable by ultrasensitive quantitative assay followed by viral loads every one to three months.
2. Monthly laboratory testing to monitor for toxicities to antiretroviral agents:
  - i. CBC
  - ii. LFTs

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- iii. Electrolytes (including anion gap)
- iv. Renal function studies if patient is taking tenofovir
- 3. Quarterly T-cell subsets
- 4. Postpartum contraception counseling

IV. **Management of Labor and Delivery**

- A. Women who have received antiretroviral therapy during the antenatal period.
- 1. Route of Delivery According to Viral Load (ACOG Committee Opinion, No. 234, May 2000)
    - a. Viral load should be obtained around 36 weeks estimated gestational age to allow sufficient time for results to be available to guide management of delivery. For patients presenting at <36 weeks, use the most recent viral load results.
    - b. Women with a viral load < 1000 cpm may deliver vaginally if no other contraindication.
    - c. Women with a viral load  $\geq$  1000 cpm should be offered elective cesarean delivery.
  - 2. Management of Vaginal Delivery
    - a. Antiretroviral Medications
      - i. IV zidovudine (see Administration guidelines in Section VI. below)  
IV zidovudine should be initiated as soon as possible upon admission for labor according to the dosing protocol outlined elsewhere in this document.
      - ii. Management of other antiretroviral agents  
Most HIV infected women receiving antiretroviral therapy antenatally will be taking 3 or 4 antiretroviral agents. Patients should continue to receive the oral component of their medications throughout the duration of their labor with the exception of zidovudine which she will receive via the IV route. For example; a woman receiving nelfinavir, lamivudine and zidovudine should continue to receive nelfinavir and lamivudine orally at the appropriate time (every 12 hours) as long as she is receiving IV zidovudine.
      - iii. Zidovudine / stavudine antagonism  
Zidovudine and stavudine are antagonistic when given concurrently and will lose their ability to inhibit HIV replication. Patients receiving stavudine antenatally should have their perinatal record reviewed as to the reason that the patient is on stavudine rather than zidovudine. If zidovudine is not contraindicated either of the following options are appropriate:
        - aa. Continue stavudine orally during management of labor and delivery.
        - bb. Discontinue stavudine and substitute IV zidovudine during management of labor and delivery.If stavudine is being taken by the patient because of a significant adverse event resulting from zidovudine use, IV zidovudine should not be given and the patient should receive oral stavudine during labor.
    - b. Labor management – Epidural catheters are NOT contraindicated in HIV positive women. However, avoid procedures that will increase the fetus' exposure to maternal blood and body fluids such as:
      - i. Scalp electrode placement
      - ii. Fetal scalp sampling
      - iii. Amniocentesis
      - iv. Amniotomy
      - v. Episiotomy

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- vi. Instrumental delivery
  - vii. External version
  - c. Post-partum management – Breastfeeding is contraindicated
    - i. After delivery of infant, IV zidovudine infusion may be discontinued immediately.
    - ii. Pediatric Service should be notified of the delivery of an infant to an HIV infected mother as soon as possible as the infant should be initiated on HIV prophylaxis in a timely fashion.
    - iii. Consult perinatal record regarding the post-partum management of antiretroviral therapy in the mother.
      - a. Some patients will continue with their antiretroviral regimen after delivery.

For those women who will continue their antiretroviral regimens after delivery, it is essential that there be no interruption in their scheduled medications and that they should receive the identical regimen that they received antenatally unless otherwise contraindicated.
      - b. Some patients will stop their antiretroviral regimen after delivery.

**It is essential that for those women who will stop their regimen, that all antiretroviral agents be discontinued together and abruptly to minimize the risk of resistance.**
3. Management of Elective Cesarean Delivery
- NOTE: For women presenting late in pregnancy for care or women with a viral load >1000 cpm**
- a. Elective cesarean delivery should be scheduled as soon as possible after 38 weeks to minimize possibility of patient presenting in labor or with SRM.
  - b. Patient should be NPO after midnight prior to planned surgery with the exception of her antiretroviral agents and other essential medications which may be taken with sips of water at the appropriate time prior to surgery.
  - c. Patients should have IV zidovudine infusion begun **at least 3 hours** prior to start of surgery to achieve steady state of zidovudine between maternal and fetal compartments.
  - d. Cesarean section should not be performed solely for the reduction of risk of perinatal HIV transmission if the patient presents in labor or she has experienced SRM prior to her arrival on L&D. The effectiveness of cesarean delivery in reducing risk of perinatal transmission in these situations is (?reduced).
  - e. Perioperative antibiotics should be given to the patient undergoing elective cesarean delivery.
4. Concomitant Use of Methergine with Certain Antiretroviral Agents
- Methergine is contraindicated in the management of post-partum hemorrhage if the patient has been receiving a protease inhibitor or a non-nucleoside reverse transcriptase inhibitor during the antenatal period and/or during the intra-partum period. Severe ergotism may result from co-administration of these agents (see table below).**
5. Concomitant Use of Combination Hormonal Contraception with Certain Antiretroviral Agents
- a. In patients taking protease inhibitors or non-nucleoside reverse transcriptase inhibitors, there are altered levels of the estrogen and progestin components of the contraception (usually decreased). Because of this and its undefined effect on contraceptive efficacy,

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an alternative form of contraception should be given to the patient prior to discharge if the patient is to continue with antiretroviral therapy with the aforementioned agents (see table below).

Antiretroviral	Methergine	Combination Contraceptives
Indinavir (PI)	<b>Contraindicated</b>	Use alternate method
Ritonavir (PI)	<b>Contraindicated</b>	Use alternate method
Saquinavir (PI)	<b>Contraindicated</b>	No data
Nelfinavir (PI)	<b>Contraindicated</b>	Use alternate method
Amprenavir (PI)	<b>Contraindicated</b>	Use alternate method
Fosamprenavir (PI)	<b>Contraindicated</b>	Use alternate method
Lopinavir + Ritonavir (PI)	<b>Contraindicated</b>	Use alternate method
Atazanavir (PI)	<b>Contraindicated</b>	Use alternate method
Nevirapine (NNRTI)	Not contraindicated	Use alternate method
Delavirdine (NNRTI)	<b>Contraindicated</b>	Use alternate method
Efavirenz (NNRTI)	<b>Contraindicated</b>	Use alternate method

V. **Intrapartum Zidovudine Administration**

A. Procedure for Zidovudine Administration

1. Start IV zidovudine as soon as possible (minimum 3 hours prior to scheduled Cesarean section).
2. Start separate peripheral line
3. Administer zidovudine with a continuous infusion device.
  - a. Loading dose: 2 mg/kg suspended in 50 cc of D5W to be administered over one hour (maximum concentration of 4 mg/ml) followed by
  - b. Maintenance dose: 1 mg/kg/hour.
4. Discontinue zidovudine following cord clamping.

B. Resume zidovudine orally postpartum if clinically indicated.

VI. **Management of HIV Infected Women Who Did Not Receive Antenatal Antiretroviral Therapy or Newly Diagnosed HIV Infected Women**

Rarely, a patient who is known to be HIV infected but has not received antiretroviral therapy during the antenatal time period may present in labor. With the implementation of **rapid HIV testing in the L&D** setting, other women may be identified as HIV infected who were not previously tested. In either case, intervention should be considered to reduce the risk of vertical transmission of HIV. **There are 3 intrapartum interventions that have been demonstrated to significantly reduce the risk of perinatal transmission of HIV.** The 4<sup>th</sup> listed regimen is theoretical and efficacy data is lacking.

Drug Regimen	Maternal Intrapartum	Newborn Postpartum
Single dose nevirapine	Nevirapine 200 mg orally	Nevirapine 2 mg/kg orally at 48 to 72 hours of age

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Intravenous zidovudine	Zidovudine 2 mg/kg loading dose given over one hour followed by 1 mg/kg/hr maintenance	2 mg/kg orally every 6 hours for 6 weeks postpartum
Oral zidovudine and oral lamivudine	Zidovudine 600 mg orally initial dose followed by 300 mg orally every 3 hours until delivery AND lamivudine 150 mg orally every 12 hours until delivery	Zidovudine 4 mg/kg every 12 hours AND lamivudine 2 mg/kg every 12 hours for 7 days after delivery
Intravenous zidovudine and single dose nevirapine	Zidovudine 2 mg/kg loading dose given over one hour followed by 1 mg/ kg/hr maintenance AND Nevirapine 200 mg orally	2 mg/kg orally every 6 hours for 6 weeks postpartum AND Nevirapine 2 mg/kg orally at 48 to 72 hours of age

Logistically, single dose nevirapine given to the mother in the course of labor is most efficacious and has become the predominant strategy to reduce the risk of vertical transmission of HIV in resource poor settings. However, nevirapine use is associated with a significant risk of induction of viral resistance, even after single dose exposure. Currently, there is limited data that suggests that the risk of resistance can be reduced with the subsequent administration of additional antiretroviral agents. A consensus has been developed based upon the most current information between representatives from Obstetrics and Gynecology (M. Vajaranant, MD), Infectious Diseases (R. Hershov, MD), Pediatrics (K. Hayani, MD) and Pharmacy (R. Jain, PharmD) to address these issues and this group recommends the following regimen to reduce the risk of vertical transmission of HIV and to reduce the risk of subsequent nevirapine resistance in previously untreated or recently diagnosed pregnant women presenting in labor:

1. Single dose nevirapine, 200 mg, given to mother orally as soon as the diagnosis of labor is made. Nevirapine is available in single 200 mg doses in the 4<sup>th</sup> floor satellite pharmacy and can be obtained and administered within minutes of a STAT order.
2. As soon as possible after delivery, the following regimen should be initiated for the mother and continued for six weeks post-partum (all medications should be discontinued in the event of a false positive HIV test).
  - a. Combivir (zidovudine 300 mg + lamivudine 150 mg), 1 tablet orally every 12 hours
  - b. Kaletra (lopinavir 133.3 mg + ritonavir 33.3 mg), 3 capsules orally with food every 12 hours
3. Infectious disease consultation should be obtained as soon as possible and prior to discharge from the hospital.
4. The patient should be provided with an adequate supply of medications to last the six week post-partum course prior to discharge.

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APPENDIX 1:

**Perinatal Rapid HIV Counseling /Testing Implementation Policy**

4/8/05

Purpose:

1. To facilitate implementation of the Illinois Law, 410 ILCS – Perinatal HIV Prevention Act and provide guidelines in accordance with the requirements for HIV confidentiality, counseling and testing of pregnant women and infants as set forth in Illinois Law, 410 ILCS 335/10.
2. To increase awareness of the HIV status of all pregnant women and to reduce perinatal HIV transmission.
3. To provide continuity of care and compliance across clinical areas.

Procedures:

1. At the time of admission the RN will check for documented HIV results during the current pregnancy for all pregnant women. (*Efforts will be made to obtain proof of HIV testing during the current pregnancy, if results are not documented in Gemini or MARS*)
2. Any documented current pregnancy HIV test result from another site will be recorded in the patient's medical record by the provider. (In MARS under "Labs")
3. Standard HIV Testing (Elisa) All pregnant patients early in gestation or who do not have conditions increasing the risk of delivery and who do not have a documented HIV test result during the current pregnancy will be counseled regarding the importance of HIV testing and will be offered HIV Elisa testing. (*HIV Elisa tests are processed Mondays, Wednesdays and Fridays except for holidays*) *The woman should be counseled regarding Rapid HIV testing if the Clinician is concerned about having the HIV results available quickly.*
4. Rapid HIV Testing : All pregnant patients presenting with the potential for delivering a viable fetus during this admission, who do not have a documented HIV test result during the current pregnancy, will be counseled regarding the availability of Rapid HIV testing and will be offered the Rapid HIV test. .
5. The RN will initiate counseling regarding Rapid HIV Testing for all eligible patients using the flipchart (available in English or Spanish) which includes the following **mandatory** information:
  - a. The benefits of HIV testing for a pregnant woman, including the prevention of transmission of the HIV virus to the fetus.
  - b. The benefits of HIV testing for the newborn infant, including interventions to prevent HIV transmission.
  - c. The side effects of interventions to prevent HIV transmission.
  - d. The statutory confidentiality provisions that relate to HIV and acquired immune deficiency syndrome testing.
  - e. The voluntary nature of the testing, including the opportunity to refuse testing of a newborn infant in writing.

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6. After the mother is counseled regarding the importance of Rapid HIV testing by the nurse, consent will be obtained by the provider. **If the mother declines testing for herself the infant will automatically be tested unless the mother refuses in writing.**
7. Testing Procedure: Rapid Testing

Mother - Blood will be drawn by the RN using a **red top** tube. (The test requires at least 7 cc of blood). The sample will be accompanied with a copy of the maternal consent and a requisition which should include the following information:

  - Orders indicating that both Rapid and Elisa HIV testing is to be done
  - The test is to be run “STAT”
  - The unit phone number Lab Personnel should call with the results.

Newborn - The Nurse will draw 2 full gold bullets and send the bullets to the Lab accompanied by a lab requisition which includes the same information as indicated above for maternal samples. **NO consent is necessary for the baby.**
8. The Nurse will call the Lab at 6-3975 to alert them a sample is being sent for rapid HIV testing.
9. The Lab will notify the charge nurse with the result and post the result in Gemini within 40-60 minutes from receipt of the specimen. The Lab will call the following numbers as appropriate with the results:
  - Labor and Delivery - 6-4175
  - Mother / Baby Unit - 6-4120
  - Neonatal Intensive Care: - 6-4150
10. Lab Personnel will initiate confirmatory testing by ELISA on all HIV Rapid Test specimens and Western Blot for all preliminary positive test results.
11. The RN will notify the Senior OB Resident/Attending Physician, Family Medicine Attending or CNM as appropriate with all positive newly diagnosed HIV Rapid Test results. The Pediatric resident will be called prior to delivery to order newborn therapy.
12. The Primary Care Provider will:
  - Notify patients of their Rapid Test results (negative or positive) as soon as possible.
  - Perform Post –Test Counseling.
  - Refer all HIV positive women and infants to the WITS Program for further continuity of care. (WITS pager -3997)
13. OB and Family Medicine (FM) will order antiretroviral medication following hospital treatment guidelines for all women testing HIV positive.
14. The primary Nurse will notify the LD Clerk as soon as the baby is born, so that the LD Clerk can facilitate the admitting process for the baby by calling Registration at **6-0341** and informing them that this baby is a “STAT, STAT” admission.
15. The Pediatric Resident or the Family Medicine Resident will contact Dr. Hayani (pager # 3651) regarding the medication regimen for newly diagnosed HIV positive, non-WITS infants.

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- HIV exposed infants should receive their first dose of AZT syrup 2.0 mg. /kg [or 1.5 mg/kg IV] as soon as possible after birth in LDR.)
  
  - Women participating in the WITS program during prenatal care will continue to have their newborn's care managed via current WITS program procedures
16. Women who declined or were not offered HIV testing intrapartum should be re-approached and re-counseled postpartum by the newborn provider regarding the benefit of testing the newborn for HIV. If the mother refuses testing for herself and the baby after two counseling efforts, the "Lab copy" of the Consent for Rapid Testing will be placed in *The Rapid HIV Test Double Refusal Log* kept in a drawer in the Mother / Baby Unit.
17. In the event a mother's HIV status is not known, but the baby tests positive, the Pediatric Provider or the Family Medicine Provider will contact the mother's OB Provider regarding the results.
18. Patient's HIV status **must be** included in the nurse to nurse report (L&D-4 West; L&D-NICU/ICN).
19. Prior to discharge, a 6 week supply of anti-viral medications for both the baby and the mother must be obtained by coordinating with the Pharm D on call (pager #4958).
20. Statistics related to the operation of the Program for Rapid HIV Testing will be coordinated by an ANI in Labor and Delivery.

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**PROTOCOL CROSS REFERENCE**

Immunizations in Pregnancy

**REFERENCES**

<http://www.cdc.gov/hiv/pubs/guidelines.htm>

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