

PURPOSE: To establish guidelines for the determination of risk status and antiretroviral prophylaxis for infants with perinatal exposure to HIV.

I. DETERMINATION OF INFANT RISK STATUS

- A. High Risk for HIV infection is defined as AT LEAST ONE of the following:
- Infants born < 33 weeks gestation
 - Infants born to women whose HIV viral load was detectable (anything greater than 20 copies/mL) after 28 0/7 weeks gestation
 - Infants born to women who did not receive antepartum antiretroviral therapy
 - Infants born to women who started antiretroviral therapy after 13 0/7 weeks gestation
 - Infants born to women who became infected with HIV or seroconverted during pregnancy
 - Infants born to women diagnosed with HIV during labor or postpartum
- B. Low Risk for HIV infection
- All other infants

II. ANTIRETROVIRAL PROPHYLAXIS RECOMMENDATIONS BY RISK STATUS

(See dosing tables for individual drugs in Section III)

- A. Infants at LOW RISK:
1. Zidovudine (ZDV or AZT): See Dosing table in Section III
 2. Initiate as soon as possible after delivery, with the goal of within 1 hour
 3. ZDV should be given from birth through **4 weeks of age**
 4. Special dosing considerations for premature infants as noted in dosing table
- B. Infants at HIGH RISK: ZDV and additional antiretrovirals as detailed below
1. Zidovudine (ZDV or AZT): See dosing table in Section III
 - a. Initiate as soon as possible after delivery, with the goal of within 1 hour
 - b. ZDV should be given from birth through **6 weeks of age**
 - c. Special dosing considerations for premature infants as noted in dosing table
 2. Nevirapine (NVP or Viramune): See dosing table in Section III
 - a. Initiate as soon as possible after delivery until the results of the birth PCR are available
 - If birth PCR negative → complete at least 4 consecutive days of Nevirapine (Viramune), then discontinue
 - If birth PCR positive → **consult with pediatric HIV specialist**
 3. Lamivudine (3TC): See dosing table in Section III
 - a. Initiate as soon as possible after delivery until the results of the birth PCR are available
 - If birth PCR negative → continue 3TC for 2 weeks from date of NVP (Viramune) discontinuation
 - If birth PCR positive → **consult with pediatric HIV specialist**
 4. Monitoring for possible drug toxicity:
 - If Nevirapine (Viramune) is given for ≥ 1 week → obtain ALT (SGPT)
 - If Lamivudine is given for ≥ 3 weeks → obtain CBC with differential

III. DOSING TABLES FOR ANTIRETROVIRAL DRUGS

Antiretroviral Drug	Gestation at Birth Dosing	Duration								
<p>Zidovudine** (ZDV or AZT)</p>	<p>≥ 35 Weeks Gestation at Birth:</p> <ul style="list-style-type: none"> • Birth to age 6 weeks: 4 mg/kg orally twice daily <p>Simplified Weight-Band Dosing for Infants ≥ 35 Weeks:</p> <table border="1" data-bbox="548 604 1097 940"> <thead> <tr> <th>Weight Band (kg)</th> <th>Volume (mL) ZDV 10 mg/mL Oral Syrup BID</th> </tr> </thead> <tbody> <tr> <td>2 to < 3 kg</td> <td>1 mL</td> </tr> <tr> <td>3 to < 4 kg</td> <td>1.5 mL</td> </tr> <tr> <td>4 to < 5 kg</td> <td>2 mL</td> </tr> </tbody> </table> <p>30 to < 35 Weeks Gestation at Birth:</p> <ul style="list-style-type: none"> • Birth to age 2 weeks: 2 mg/kg orally twice daily • Age 2 weeks to 4-6 weeks: 3 mg/kg orally twice daily <p>< 30 Weeks Gestation at Birth:</p> <ul style="list-style-type: none"> • Birth to age 4 weeks: 2mg/kg orally twice daily • Age 4 to 6 weeks: 3mg/kg orally twice daily 	Weight Band (kg)	Volume (mL) ZDV 10 mg/mL Oral Syrup BID	2 to < 3 kg	1 mL	3 to < 4 kg	1.5 mL	4 to < 5 kg	2 mL	<p>Birth through 4 weeks for LOW RISK</p> <p>Birth through 6 weeks for HIGH RISK</p>
Weight Band (kg)	Volume (mL) ZDV 10 mg/mL Oral Syrup BID									
2 to < 3 kg	1 mL									
3 to < 4 kg	1.5 mL									
4 to < 5 kg	2 mL									
<p>Lamivudine++ (3TC)</p>	<p>≥ 32 Weeks Gestation at Birth:</p> <ul style="list-style-type: none"> • Birth to age 4 Weeks: 2 mg/kg orally twice daily <p>< 32 Weeks Gestation at Birth:</p> <ul style="list-style-type: none"> • Contact 24/7 Illinois Perinatal HIV Hotline: 1-800-439-4079 	<p>Duration pending PCR result</p>								
<p>Nevirapine++ (NVP or Viramune)</p>	<p>≥ 37 Weeks Gestation at Birth:</p> <ul style="list-style-type: none"> • Birth to age 6 Weeks: 6 mg/kg orally twice daily <p>34 - < 37 Weeks Gestation at Birth:</p> <ul style="list-style-type: none"> • Birth to age 1 week: 4 mg/kg orally twice daily x 1 week • Age 1 week – 6 weeks: 6mg/kg orally twice daily <p>< 34 Weeks Gestation at Birth:</p> <ul style="list-style-type: none"> • Contact 24/7 Illinois Perinatal HIV Hotline: 1-800-439-4079 	<p>Duration pending PCR result</p>								

** For infants unable to tolerate oral agents, the IV dose for ZDV is 75% of the oral dose

++ There is no IV formulation for 3TC or NVP (Viramune); NPO infants are not candidates for this treatment.

IV. INFANT TESTING AND FOLLOW UP

A. Low Risk Infant

1. Perform HIV DNA PCR or RNA PCR or Total Nucleic Acid (TNA)*** at:
 - ≥ 2 weeks of age
 - ≥ 6 weeks of age
 - ≥ 4 months of age
2. **Any infant with a positive PCR or TNA should be immediately referred to a pediatric HIV specialist**
3. Obtain CBC at birth (consider HBsAg, HCV Ab, RPR based on maternal history)
4. Obtain HIV antibody test at 12 months of age (repeat every 6 months until negative)

B. High Risk Infant

1. **At Birth, perform HIV DNA PCR or RNA PCR or Total Nucleic Acid (TNA)*****
 - **Send expedited HIV DNA PCR or RNA PCR or TNA (whichever has the shortest turnaround time) at birth; goal is to have results available within 1 week**
 - **Contact the 24/7 Illinois Perinatal HIV Hotline at 1-800-439-4079 for assistance with expedited testing or if unable to receive PCR or TNA results within 1 week**
2. Perform HIV DNA PCR or RNA PCR or TNA (not expedited) at:
 - ≥ 2 weeks of age
 - ≥ 8 weeks of age
 - ≥ 4 months of age
3. **Any infant with a positive PCR or TNA should be immediately referred to a pediatric HIV specialist**
4. Obtain CBC at birth (consider HBsAg, HCV Ab, RPR based on maternal history)
5. Obtain urine for CMV PCR before 3 weeks of age
6. Obtain HIV antibody test at 12 months of age (repeat every 6 months until negative)

***** HIV RNA PCR or TNA is preferred for infants born to mothers who acquired HIV outside of the US or Europe who may be infected with non-clade B viral subtype**

V. PCP PROPHYLAXIS

- A. PCP prophylaxis is recommended beginning at 6 weeks of age ONLY for infants with a **positive** DNA PCR or RNA PCR or TNA → **Consult with pediatric HIV specialist**
- B. PCP prophylaxis is NO LONGER recommended if the DNA PCR or RNA PCR or TNA performed at ≥ 2 weeks and $\geq 6-8$ weeks of age are negative

Approved: 4/13/2017

The 24/7 Illinois Perinatal HIV Hotline's *GUIDELINES FOR CARE OF INFANTS WITH PERINATAL EXPOSURE TO HIV* were developed in conjunction with Dr. Ellen Chadwick and Dr. Ram Yogev, Directors, Section of Pediatric and Maternal HIV Infection at Ann & Robert H. Lurie Children's Hospital of Chicago.