HIV/AIDS—Prenatal Care for HIV+ Mothers

1. Algorithm for Prenatal Screening & Care (Antepartum)
2. Algorithm for Prenatal HIV Screening and Care (Mother refuses screening)
3. Algorithm for Intrapartum Care
4. Prenatal Care for HIV+ Mothers
   a. Background
   b. Testing & Referral
   c. Newly diagnosed HIV in pregnancy
   d. Antiretroviral Therapy Guidelines for Obstetric Management of HIV
5. Route of Delivery
6. Neonatal prophylaxis for infants born to HIV positive mothers or infants born to mothers with an unconfirmed preliminary positive HIV test:
7. Labor and Delivery Orders for HIV Infected Women
8. Zidovudine Dosing for HIV in Pregnancy (Chart)
9. Appendix A: Antiretroviral Therapy in Pregnancy Alternative Regimens
10. References

Developed by:
Beth Saltonstall, MD  x2907
July 2006
PIC Approval Date:  8/3/2006
Updated: 3/11/2013
Updated 12/29/2015
Updated 5/14/2018

This guideline is designed for general use for most adult patients, but may need to be adapted to meet the special needs of a specific patient as determined by the patient’s provider.
Algorithm for Prenatal HIV Screening & Care (Antepartum)

HIV screening at 1st prenatal visit (opt out)

Pt. opts-in for testing

Optional pre-test counseling

Screen for HIV

HIV Combo Screen Negative

Rescreen at 36 weeks*

Assess mom for risk, if high risk consider PrEP and/or review of acute HIV and rescreen more often

Notify of status in person & offer post-test counseling

Draw baseline labs 1st trimester ultrasound recommended for confirmation of gestational age and potential timing for cesarean delivery, if needed.

Pt. makes EIS appointment

Refer to EIS x2907

No EIS appl.

Provider consult with EIS (x2907) or ID consult on-call for HAART regimen

If patient previously diagnosed as HIV+ and currently on HAART, continue current regimen unless contraindicated.

Consult with EIS (x2907) or ID consult on-call for HAART regimen

Offer HAART ASAP

CD4 and Viral Load labs every trimester; if CD4<200 initiate PCP prophylaxis

If Viral Load >1000 copies/mL, counsel patient on potential benefit of scheduled cesarean delivery at 38 weeks.

See Intrapartum guidelines

This guideline is designed for general use for most patients, but may need to be adapted to meet the special needs of a specific patient as determined by the patient's provider.

*ANMC has decided to rescreen all pregnant women at 36 weeks for HIV, Gonorrhea, and Chlamydia.
Algorithm for Prenatal HIV Screening & Care (Mother refuses screen)

1. HIV screening at 1st prenatal visit (opt out)
   - Pt. refuses
     - Offer counseling, educate on risk factors and possibility of transmission to baby

2. HIV Negative by rapid test
   - Offer rapid and 4th gen screen at 36 weeks*
   - HIV screen Positive
     - Follow Antepartum/Intrapartum guidelines
     - Reflex confirmatory for mother and Send PCR for infant.
     - If confirmatory & PCR negative stop protocol

3. If mother refuses screening test infant HIV-screen (This will show if mom is positive because will be screening maternal antibodies)
   - If HIV screen positive start infant on ZDV protocol and draw PCR on infant
   - If PCR negative, continue ZDV protocol as probable exposed infant.
   - If PCR is positive, consult ID on call or EIS (x2907)

4. IF Mom’s confirmatory test = positive
   - Baby PCR = negative, continue infant ZDV per protocol for exposed infant.

5. IF Mom’s confirmatory test = positive
   - Baby PCR = positive, Consult ID on call or EIS (x2907)

This guideline is designed for general use for most patients, but may need to be adapted to meet the special needs of a specific patient as determined by the patient’s provider.

*ANMC has decided to rescreen all pregnant women at 36 weeks for HIV, Gonorrhea, and Chlamydia
Algorithm for Intrapartum Care

Do NOT stop HAART during labor or for planned cesarean delivery even if patient is NPO (unless prescribed ZDV and starting IV ZDV—see below, stop the ZDV PO while infusing IV.)

If Viral Load <1000 at 36 weeks or unknown
If Viral Load >1000 at 36 weeks or unknown

Begin IV ZDV at presentation for labor or 3 hours before scheduled cesarean delivery

Avoid invasive monitoring (s.a. fetal scalp monitor);
Avoid invasive procedures (s.a. forceps, vacuum)

ZDV loading dose = 2mg/kg over 1 hour

After loading dose, begin ZDV continuous infusion at 1mg/kg/hr until delivery

Notify Pediatrics of impending birth

See Pediatric Guidelines (Follow-up for infants born to HIV+ Mothers)

Formula feed infant only. Do not give expressed maternal milk.

Notes:
1. Wash infant before any invasive procedures—Vitamin K shot, Hepatitis B vaccine, blood draw, etc.
2. If resuscitation is required, take all possible precautions to protect infant from infection. After resuscitation, contact ID or the EIS program (x2907) or the Perinatal Hotline at 1-888-448-8765 for medication recommendations.
3. Mother should not masticate food in future when infant ready for solids.

This guideline is designed for general use for most patients, but may need to be adapted to meet the special needs of a specific patient as determined by the patient’s provider.
4. Prenatal Care for HIV+ Mothers

Refer to: (http://aidsinfo.nih.gov, select Guidelines, then select Perinatal Guidelines)\(^4\) for continuously updated guidelines

The National Perinatal HIV Hotline is a federally funded service providing free clinical consultation to providers caring for HIV-infected women and their infants. *The National Perinatal HIV Hotline (1-888-448-8765)*

a. **Background**

Heterosexual contact is responsible for 90% of HIV transmission in the United States for women younger than 25 years.\(^1\) Management of HIV infection during pregnancy centers on maintaining the health of the mother and preventing transmission to her child. The American College of Obstetricians and Gynecologists (ACOG) recommends that OB/GYN providers routinely screen all women between the ages of 19 and 64 for HIV, regardless of their pregnancy status or risk factors. They also recommend targeted screening for women outside this age range who are at high risk. High risk is defined as injection drug users, sexual partners with a drug user or someone infected with HIV, exchanging sex for money, diagnosis of another STD in the past year and having more than one sex partner since their last HIV screening test.\(^2\)

The ACOG also encourages “opt out” testing, in which patients are told that HIV tests will be given as part of routine care unless they decline. Neither written informed consent nor prevention counseling is required in Alaska with opt-out testing. It is important that the woman be aware that HIV and AIDS are both name based reportable diseases in Alaska.

b. **Testing and Referral:**

1. All women should be screened for HIV as early as possible in their pregnancy.\(^3\) The HIV test is administered as ‘opt out’. All clients are tested unless they specifically choose not to be tested. If the HIV test is preliminary positive, the lab automatically confirms the test. ANMC and the Alaska State Lab are using the 4\(^{th}\) generation HIV screening test which has an automatic confirmation algorithm for preliminary positive results.

2. After review of the CDC 2015 Sexually Transmitted Diseases Treatment Guidelines and OB/GYN departmental discussion, the ANMC STD Guidelines includes third trimester screening for Chlamydia, gonorrhea and HIV. Consider extragenital testing as indicated

3. Repeat HIV screening in the third trimester is recommended by ACOG for women:
• diagnosed with another STD in the last year
• who are injection drug users or exchanging sex for money
• who have a new or multiple sex partners during the pregnancy or a partner known to be HIV positive
• live in areas of high HIV prevalence defined as one HIV infected pregnant woman per 1,000 tested
• declined to be tested earlier in the pregnancy.\(^3\)
• who are under 19 years of age and are sexually active\(^1\)
• who present in labor with unknown HIV status, or a high-risk woman who presents with no 3rd trimester test, should be screened with a rapid HIV test and screen in Labor and Delivery. If the test is a preliminary positive, intrapartum treatment for the mother and prophylaxis with ZDV for the infant should not be delayed in awaiting a confirmatory test. Breast feeding should be delayed until result of confirmatory test is available.

c. **Newly Diagnosed HIV in pregnancy:**
   1. As soon as a patient is confirmed positive, they should be referred to the Early Intervention Services (EIS) clinic by contacting an EIS Case Manager at 729-2907 or 729-4209. Call 729-2907 to schedule an appointment with EIS/ID.

   2. **Baseline labs:** Laboratory data including CD4 count (lymphocyte subset panel 4), viral load (HIV PCR), HIV genotyping, fasting lipids and glucose, comprehensive chemistry panel, CBC, Toxoplasmosis IgG, CMV IgG, syphilis screen, and chronic hepatitis screening for A, B and C, should be drawn prior to EIS appointment if possible. Aptima for GC/CT/Trich at all exposed sites should be obtained. A QuantiFERON should be drawn if no history of prior tuberculosis infection.

   3. **Antiretroviral Pregnancy Registry:**
      All women who are seen in the EIS clinic will have anonymous entry into the Antiretroviral Pregnancy Registry as recommended by the Perinatal Guidelines.\(^4\) This international registry is designed to follow the pregnancies and infants born of these pregnancies to determine if there are detrimental effects of antiretroviral therapy on the health and well-being of the pregnancies or the infants born.

      Each patient will be given an anonymous registry number through the 1-800-258-4263 Antiretroviral Pregnancy Registry. EIS will be responsible for the birth outcome follow-up sent to the Registry.

   4. **Invasive antenatal procedures**
      If chorionic villus sampling, cordocentesis or amniocentesis is necessary, it should be performed only after the HIV positive
woman has been on combination antiretroviral therapy and ideally when the viral load has been determined to be <20. If >20, consult with an expert.

Of note is that no transmissions of HIV to a fetus from these procedures have been recorded in patients on HAART, but a small risk of transmission cannot be ruled out. Some experts view chorionic villus sampling and cordocentesis as too risky and suggest limiting procedures to amniocentesis. In those women without the benefit of HAART, there is a clear increased risk of transmission from mother to fetus.4

d. Anti-retroviral Therapy Guidelines for Obstetric Management of HIV

1. Use of ARV therapy in prevention of perinatal HIV transmission: Combination drug therapy, Anti-Retroviral Therapy (ART) is the current standard of care for both the treatment of HIV infection and the prevention of perinatal HIV transmission. Antiretroviral (ARV) drugs reduce perinatal transmission by several mechanisms including lowering maternal antepartum viral load, and pre- and post-exposure prophylaxis of the infant. Through the use of the antiretroviral therapy after the first trimester, in addition to the intrapartum Zidovudine (Retrovir or ZDV) regimen (if indicated) and infant ZDV protocol, the possibility of mother to infant transmission is reduced from approximately 25% to less than 2%. Using this strategy, there are less than 200 HIV infected infants born in the United States each year. These infected infants are generally born to mothers who had primary HIV infection during the pregnancy, women who breastfed their infants, had poor adherence to antiretrovirals, delayed or no prenatal care and lack of universal prenatal HIV counseling and testing. Therefore, for prevention of perinatal HIV transmission, in addition to screening, combined antepartum, intrapartum and infant antiretroviral prophylaxis is recommended.4

Known benefits and potential risks of antiretroviral use during pregnancy should be discussed with all HIV positive pregnant women. Review the pros and cons of antiretroviral therapy in treatment naïve patients in the Initiating Antiretroviral Therapy in Treatment–Naïve Patients section of the US DHHS Antiretroviral Guidelines for Adults and Adolescents.5

Discussions with women about initiation of ARV drug regimens should include information about4:

a. maternal risk of disease progression and the benefits and risks of initiation of therapy for maternal health;
b. benefit of combination ARV regimens for preventing perinatal transmission of HIV;
c. benefits of therapy for reducing sexual transmission to discordant partners when viral suppression is maintained;
d. potential adverse effects of ARV drugs for mothers, fetuses, and infants, including potential interactions with other medications the women may already be receiving;
e. the limited long-term outcome data for both women who temporarily use ARV drugs during pregnancy for prophylaxis of transmission and infants with in utero drug exposure; and
f. the need for strict adherence to the prescribed drug regimen to avoid resistance.

Pregnant women should make an informed choice, after counseling and discussion, on whether to take antiretroviral drugs for prevention of mother-to-child transmission or to follow other medical recommendations intended to decrease perinatal HIV transmission. This choice should be respected.

2. Antepartum:

Since controlled viral load has been shown to be the most important factor in decreased transmission of HIV to a fetus/neonate, the focus of the guidelines is to promote adherence and tolerability of an HIV ARV regimen.

A. Combination HAART should be discussed and initiated asap during the first trimester for all HIV positive pregnant patients regardless of their clinical, immunologic, or virologic status.

B. Preferred regimens are outline in Table 6 from the Perinatal Guidelines.

C. Clients not on ART: If the HIV RNA bDNA (viral load) is >500 copies/mL, HIV resistance/genotypic testing is recommended for all pregnant women. Start recommended ART regimen asap, prior to receiving genotype results.

D. If HIV is diagnosed later in pregnancy, ART therapy should be initiated promptly without waiting for results of resistance testing.

E. Undetectable or <20 viral load using HIV RNA PCR and the regimen is well tolerated, women who are already taking HAART should be continued on their current regimen unless contraindicated. Resistance testing should be done in women who are on HAART but do not have full viral suppression (HIV RNA levels >500 copies/mL) to select a new regimen.
with a greater likelihood of suppressing viral replication to undetectable levels. It should also be considered when HIV RNA levels <500 copies/mL though it may be unsuccessful.\textsuperscript{4}

In pregnant women, as in non-pregnant adults, a combination ARV treatment regimen with at least three agents is recommended.

An ARV regimen including two NRTIs combined with a PI with low-dose ritonavir or an integrase inhibitor is preferable.

**Table 6. What to Start: Initial Combination Regimens for Antiretroviral-Naive Pregnant Women**

These recommendations are for pregnant women who have never received antiretroviral therapy (ART) previously (i.e., antiretroviral-naive) and who have no evidence of significant resistance to regimen components. See Table 9 for more information on specific drugs and dosing in pregnancy.

Within each drug class and recommendation category, regimens are listed alphabetically, and the order does not indicate a ranking of preference. In addition, The Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission (the Panel) makes no recommendation of one agent or regimen over another within each category (Preferred or Alternative).

It is recommended that women who become pregnant while on a stable ART regimen with viral suppression remain on that same regimen, with the exception of regimens containing didanosine, stavudine, or treatment-dose ritonavir, and (until more data are available) elvitegravir/cobicistat.

**Table 6. What to Start: Initial Combination Regimens for Antiretroviral-Naive Pregnant Women**

**Preferred Initial Regimens in Pregnancy:**

Drugs or drug combinations are designated as Preferred for initiating ART in ARV-naive pregnant women when clinical trial data in adults have demonstrated optimal efficacy and durability with acceptable toxicity and ease of use; pregnancy-specific PK data are available to guide dosing; in addition, there have been no established associations with teratogenic effects (from animal and/or human studies), and no clinically significant adverse outcomes for mothers, fetuses, or newborns have been reported.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 6. What to Start: Initial Combination Regimens for Antiretroviral-Naive Pregnant Women

**Preferred Initial Regimens in Pregnancy:**
Drugs or drug combinations are designated as Preferred for initiating ART in ARV-naive pregnant women when clinical trial data in adults have demonstrated optimal efficacy and durability with acceptable toxicity and ease of use; pregnancy-specific PK data are available to guide dosing; in addition, there have been no established associations with teratogenic effects (from animal and/or human studies), and no clinically significant adverse outcomes for mothers, fetuses, or newborns have been reported.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preferred Two-NRTI Backbones</strong></td>
<td></td>
</tr>
<tr>
<td>ABC/3TC</td>
<td>Available as FDC. Can be administered once daily. ABC should not be used in patients who test positive for HLA-B*5701 because of risk of hypersensitivity reaction. ABC/3TC with ATV/r or with EFV is not recommended if pretreatment HIV RNA is &gt;100,000 copies/mL.</td>
</tr>
<tr>
<td>TDF/FTC or TDF/3TC</td>
<td>TDF/FTC available as FDC. Either TDF/FTC (coformulated) or TDF with separate 3TC can be administered once daily. TDF has potential renal toxicity, thus TDF-based dual NRTI combinations should be used with caution in patients with renal insufficiency.</td>
</tr>
</tbody>
</table>

**Preferred PI Regimens**

<table>
<thead>
<tr>
<th>ATV/r plus a Preferred Two-NRTI Backbone</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Once-daily administration. Extensive experience in pregnancy. Maternal hyperbilirubinemia; no clinically significant neonatal hyperbilirubinemia or kernicterus reported, but neonatal bilirubin monitoring recommended. Cannot be administered with proton-pump inhibitors; specific timing recommended for dosing with H2 blockers (see Table 9).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DRV/r plus a Preferred Two-NRTI Backbone</th>
<th>Better tolerated than LPV/r. PK data available. Increasing experience with use in pregnancy. Must be used twice daily in pregnancy.</th>
</tr>
</thead>
</table>

**Preferred Integrase Inhibitor Regimen(s)**

| RAL plus a Preferred Two-NRTI Backbone | PK data available and increasing experience in pregnancy. Rapid viral load reduction (potential role for women who present for initial therapy late in pregnancy). Useful when drug interactions with PI regimens are a concern. Twice-daily dosing required. |
Consult ID/EIS or the online Perinatal Guidelines, Table 6 for alternative regimens.

E. **Contraindications to ART & other Medications:**

a. Women with CD4 >250 cells/mm$^3$ have increased risk of developing symptomatic, often rash-associated, nevirapine-related hepatotoxicity which can be severe, life-threatening, and in some cases fatal. ACOG recommends that nevirapine be avoided during pregnancy due to hepatotoxicity.$^4$ The Public Health Service Task Force recommends that nevirapine only be used as a component of a combination regimen when ART is initiated in women with CD4<250. Women who enter pregnancy on nevirapine and are tolerating it well may continue regardless of their CD4 count.$^4$

F. **Labs after HAART initiation**:

   ii. Two weeks after HAART initiation or regimen change: CBC, comprehensive chemistry including liver and renal function tests, and a urinalysis

   iii. One month after initiation: CD4 and viral load, CBC and chemistry panel should be done to determine efficacy of meds and possible side effects

iv. Viral load and CD4: monthly until undetectable and then every 3 months during pregnancy to determine need for alterations in current regimen or need for initiation of PCP prophylaxis (if CD4 <200 cells/mm$^3$) or Mycobacterium avium prophylaxis (CD4 <50 cells/mm$^3$) and at 34-36 weeks gestation to inform decisions about delivery.

v. Labs should be done more frequently if viral suppression is not achieved or HAART compliance is a concern. If viral suppression is not achieved within 12 weeks of HAART initiation, consult EIS/ID (x2907).

3. **Intrapartum:**

   a. Intrapartum intravenous ZDV is recommended for HIV infected pregnant women with Viral Load >1000 copies/mL at 36 weeks regardless of their antepartum regimen.$^4$ If women did not receive antepartum ARV medications, intrapartum ZDV combined with infant ZDV prophylaxis should be given to reduce the risk of perinatal transmission from 20-30% to 9%. If ZDV was discontinued secondary to anemia, it can still be safely administered during the intrapartum period.

   b. HAART therapy should not be stopped during labor or for planned cesarean delivery even if the patient is NPO. Give oral dosing of
prescribed ARV regimen except ZDV if patient is receiving IV ZDV. If taking Stavudine (d4T) as part of antepartum regimen, d4T should be stopped during labor while ZDV is being administered (see below for ZDV intravenous guidelines).4

c. Begin intravenous ZDV at presentation for labor or 3 hours before scheduled cesarean delivery. Loading dose is 2mg/kg over 1 hour. After loading dose, begin continuous infusion of 1mg/kg/hr until delivery.4

d. If rapid HIV test is done in L&D and result is positive, initiate intravenous ZDV without waiting for results of confirmatory test. Also, initiate infant prophylactic ZDV regimen per the neonatal protocol below. If postpartum confirmatory test is positive, continue infant ZDV per guidelines below, and consult EIS/ID (ext. 2907). If negative, stop infant ZDV.

5. Route of Delivery:

a. Cesarean Delivery: Women infected with HIV who have viral loads >1,000 copies/mL should have a scheduled cesarean delivery at 38 weeks’ gestation to minimize perinatal transmission of HIV. For women with viral loads <1,000 copies/mL, cesarean delivery performed for standard obstetrical indications should be scheduled at a standard time for obstetrical indications. Data are insufficient to demonstrate a benefit for cesarean delivery of neonates in women with viral loads < 1,000 copies/mL and show no reduction in the transmission rate if cesarean delivery is performed after the onset of labor or rupture of membranes. The patient’s autonomy in making the final decision regarding route of delivery must be respected. Prophylactic antibiotics are appropriate for cesarean delivery because of the increased risk of infectious morbidity.4

b. Vaginal Delivery:
   i. In women not receiving HAART, the longer the duration of membrane rupture before delivery, the greater the risk of transmission.
   ii. In women receiving HAART, duration of ruptured membranes is NOT associated with an increased risk of perinatal transmission and vaginal delivery is recommended.

c. Obstetric procedures increasing the risk for fetal exposure to maternal blood such as amniocentesis, invasive fetal monitoring (fetal scalp monitoring) and other invasive procedures (i.e. use of forceps or vacuum) have been implicated in increasing vertical transmission rates by some investigators.4
i. Artificial rupture of membranes (ROM) performed in the setting of antiretroviral therapy (ART) and virologic suppression is not associated with increased risk of perinatal transmission and can be performed for standard obstetric indications

ii. The following should generally be avoided because of a potential increased risk of transmission, unless there are clear obstetric indications:
   1. Artificial ROM in setting of viremia
   2. Routine use of fetal scalp electrodes for fetal monitoring
   3. Operative delivery with forceps or a vacuum extractor

   d. **Postpartum Hemorrhage Contraindication:** In women receiving a cytochrome P (CYP) 3A4 enzyme inhibitor such as a protease inhibitor (such as Atazanavir (ATV, reyataz) or darunavir/ritonavir), methergine should be used only if no alternative treatments for postpartum hemorrhage are available and the need for pharmacologic treatment outweighs the risks. If methergine is used, it should be administered in the lowest effective dose for the shortest possible duration.⁴

   e. In women who are receiving a CYP3A4 enzyme inducer such as nevirapine, efavirenz, or etravirine, additional uterotonic agents may be needed because of the potential for decreased methergine levels and inadequate treatment effect

   f. **Postpartum: Formula feed only⁴.** Breastfeeding is not recommended for HIV-infected women, including those receiving ART. Do not give infant expressed maternal milk.

   g. Health care providers should routinely inquire about premastication of foods fed to infants, instruct HIV-infected caregivers to avoid this practice, and advise on safer feeding options (Initial Postnatal Management of the HIV-exposed neonate updated 7/31/2012)⁴.

5. Neonatal HIV prophylaxis for infants born to HIV-positive mothers or infants born to mothers with an unconfirmed preliminary positive HIV test:
### Table 7. Newborn Antiretroviral Management According to Risk of HIV Infection in the Newborn

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Neonatal ARV Management</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Low Risk of Perinatal HIV Transmission</strong></td>
<td>Mothers received standard ART during pregnancy with sustained viral suppression near delivery and no concerns related to adherence</td>
<td>4 weeks of ZDV</td>
</tr>
</tbody>
</table>
| **Higher Risk of Perinatal HIV Transmission**<sup>a,b</sup> | • Mothers who received neither antepartum nor intrapartum ARV drugs  
• Mothers who received only intrapartum ARV drugs  
• Mothers who received antepartum and intrapartum ARV drugs but who have detectable viral load near delivery, particularly if delivery was vaginal  
• Mothers with acute or primary HIV infection during pregnancy or breastfeeding | Combination ARV prophylaxis with 6 weeks ZDV and 3 doses of NVP (prophylaxis dosage, with doses given within 48 hours of birth, 48 hours after first dose, and 96 hours after second dose) or Empiric HIV therapy consisting of ZDV, 3TC, and NVP (treatment dosage)<sup>c</sup> |
| **Presumed Newborn HIV Exposure**         | Mothers with unknown HIV status who test positive at delivery or postpartum or whose newborns have a positive HIV antibody test | ARV management as above (for higher risk of perinatal HIV transmission). ARV management should be discontinued immediately if supplemental testing confirms that mother does not have HIV. |
| **Newborn with Confirmed HIV**<sup>e</sup> | Confirmed positive newborn HIV virologic test/NAT | 3 drug combination ARV regimen at treatment dosage |

---

<sup>a</sup> See text for evidence supporting combination ARV prophylaxis and empiric HIV therapy.  
<sup>b</sup> See the Intrapartum Care section for guidance on indications for scheduled cesarean delivery and intrapartum IV ZDV to reduce the risk of perinatal HIV transmission for mothers with elevated viral load at delivery.  
<sup>c</sup> Most experts would opt to administer empiric HIV therapy to infants with acute HIV during pregnancy because of the high risk for in utero infection. If acute HIV is diagnosed during breastfeeding, mother should stop...
breastfeeding.

* The optimal duration of empiric HIV therapy in newborns at higher risk of perinatal HIV transmission is unknown. Many experts administer 6 weeks of combination therapy; others opt to discontinue NVP and/or 3TC after the return of negative newborn testing. ZDV should be continued for 6 weeks.

* Most experts do not recommend delaying the initiation of ART while waiting for the results of the confirmatory HIV NAT, given low likelihood of false-positive HIV NAT testing.

**Note:** ARV drugs should be initiated as close to the time of birth as possible, preferably within 6 to 12 hours of delivery. See Table 8 for dosing specifics.

**Key to Acronyms:** 3TC = lamivudine; ART = antiretroviral therapy; ARV = antiretroviral; IV = intravenous; NAT = nucleic acid test; NVP = nevirapine; ZDV = zidovudine

### Table 8. Newborn Antiretroviral Dosing Recommendations

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ZDV</strong></td>
<td><strong>≥35 Weeks’ Gestation at Birth</strong></td>
</tr>
<tr>
<td>Treatment and Prophylaxis Dosage</td>
<td><em>Birth to Age 4–6 Weeks:</em></td>
</tr>
<tr>
<td></td>
<td>- 4 mg/kg/dose orally twice daily</td>
</tr>
<tr>
<td>Simplified Weight-Band Dosing for Newborns ≥35 Weeks:</td>
<td></td>
</tr>
<tr>
<td>Weight Band (kg)</td>
<td><em>Volume (mL) ZDV</em></td>
</tr>
<tr>
<td>2 to &lt;3 kg</td>
<td>10 mg/mL Oral Syrup Twice Daily</td>
</tr>
<tr>
<td>3 to &lt;4 kg</td>
<td>1.5 mL</td>
</tr>
<tr>
<td>4 to &lt;5 kg</td>
<td>2 mL</td>
</tr>
<tr>
<td>≥30 to &lt;35 Weeks’ Gestation at Birth</td>
<td><em>Birth–Age 2 Weeks:</em></td>
</tr>
<tr>
<td></td>
<td>- 2 mg/kg/dose orally twice daily</td>
</tr>
<tr>
<td>Age 2 Weeks to 4–6 Weeks:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- 3 mg/kg/dose orally twice daily</td>
</tr>
<tr>
<td>&lt;30 weeks’ Gestation at Birth</td>
<td><em>Birth–Age 4 Weeks:</em></td>
</tr>
<tr>
<td></td>
<td>-</td>
</tr>
</tbody>
</table>
**3TC**

**Treatment and Prophylaxis Dosage**

<table>
<thead>
<tr>
<th>Age Range</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth – Age 4 Weeks</td>
<td>2 mg/kg/dose orally twice daily</td>
</tr>
<tr>
<td>Age 4–6 Weeks</td>
<td>3 mg/kg/dose orally twice daily</td>
</tr>
</tbody>
</table>

**NVP**

**Prophylaxis Dosage**

- **Birth Weight 1.5–2 kg:**
  - 8-mg dose orally once daily
  - **Note:** No calculation is required for this dose; **this is the actual dose, not a mg/kg dose.**

- **Birth Weight >2 kg:**
  - 12-mg dose orally once daily
  - **Note:** No calculation is required for this dose; **this is the actual dose, not a mg/kg dose.**

**NVP**

**Treatment Dosage**

<table>
<thead>
<tr>
<th>Age Range</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth – Age 6 Weeks</td>
<td>6 mg/kg/dose orally twice daily</td>
</tr>
<tr>
<td>34 to &lt;37 Weeks’ Gestation at Birth</td>
<td>4 mg/kg/dose orally twice daily</td>
</tr>
<tr>
<td>Birth – Age 1 Week</td>
<td>4 mg/kg/dose orally twice daily</td>
</tr>
<tr>
<td>Age 1–6 Weeks</td>
<td></td>
</tr>
</tbody>
</table>

**≥32 Weeks’ Gestation at Birth**

**Birth – Age 4 Weeks:**

- 2 mg/kg/dose orally twice daily

**Age 4–6 Weeks:**

- 4 mg/kg/dose orally twice daily

**≥37 Weeks’ Gestation at Birth**

**Birth – Age 6 Weeks:**

- 6 mg/kg/dose orally twice daily
6 mg/kg/dose orally twice daily

Key to Abbreviations: 3TC = lamivudine; IV = intravenous; NVP = nevirapine; ZDV = zidovudine

c. Laboratory testing for infants:

   i. High risk infants, those born to mothers newly HIV infected during pregnancy, those with antenatal complications or with CD4 counts <200 copies/ml should have an HIV PCR drawn at birth.
   ii. For all infants, draw a CBC with differential at birth for baseline evaluation.
   iii. HIV PCR should be obtained at 14-21 days
   iv. CBC and HIV PCR at 4-6 weeks (see below on diagnosis of HIV infection in infants and children).
   v. HIV PCR at 4-6 months.
   vi. HIV screen (EIA) after 18 months of age if not definitively negative.

Diagnosis of HIV infection and presumptive lack of HIV infection in children with known exposure to perinatal HIV:

1. Definitive infection:
   Positive virologic results on two separate specimens at any age
   (confirm ANY positive test with repeat test asap)
   OR
   Age >18 months and either a positive virologic test or a positive confirmed HIV-antibody test

2. Presumptive exclusion of infection in nonbreastfed infant:
   No clinical or laboratory evidence of HIV infection
   AND
   Two negative virologic tests, both obtained at >2 weeks of age and one obtained at >4 weeks of age and no positive virologic tests
   OR
   One negative HIV antibody test at >6 months of age

3. Definitive exclusion of infection in nonbreastfed infant:
   No clinical or laboratory evidence of HIV infection
   AND
   Two negative virologic tests, both obtained at >1 month of age and one obtained at >4 months of age and no positive virologic tests
   OR
   Two or more negative HIV antibody tests at >6 months of age
4. **Medication discontinuation:**
   1. ZDV can be discontinued in the infant at the time of a preliminary HIV negative determination.
   2. PCP prophylaxis is not necessary in infants found to be preliminary or definitively negative for HIV prior to 4-6 weeks of age.
   3. PCP prophylaxis should be initiated in infants not shown to be preliminary negative at age 4-6 weeks. PCP prophylaxis can be discontinued in the infant at the time of a preliminary HIV negative determination.

Name: _____________________ MR#: ___________ Date: ______________

7. **Labor & Delivery Orders for HIV Infected Women**

1. Admit to L&D
2. Vital signs and FHT routine
3. May have clear liquid diet
4. Activity ad lib
5. IV: LR at 150 mL/hr
6. External monitors *only*
7. Do NOT place fetal scalp electrode
8. Zidovudine (ZDV) 2 mg/kg over 1 hour on admission if mother has HIV RNA (viral load) >1000 copies/mL or unknown viral load (VL) at 36 weeks*
   a. weight in pounds ____/2.2 = ____ kg;
   b. loading dose ZDV (2mg x _____kg = ____ mg ZDV over 1 hour).
9. ZDV 1 mg/kg/hour thereafter until delivered (maintenance dose = ____ mg/hr)
10. If patient is taking other anti-retroviral medications, continue them as per patient’s schedule (except d4T—stop during labor while ZDV is administered, and ZDV—give per IV route in #9 and 10 above and stop PO dosing during labor). Do NOT stop such therapy for planned surgery; patient may take with sips of water.

Signed: _______________________________ Date: _____________________
* if VL <1000 copies/mL at 36 weeks, ZDV is not required but may still be recommended
# Zidovudine Dosing for HIV in Pregnancy

<table>
<thead>
<tr>
<th>Current pregnancy weight in Pounds (Lbs)</th>
<th>Current pregnancy weight in Kilograms (Kg)</th>
<th>Loading Dose in mg (=2mg/kg over 1 hr)</th>
<th>Add loading dose (in mg) to 100ml D5W or NS, infuse mixture over 60 minutes</th>
<th>For Continuous Infusion: Withdraw 100ml from a 250 ml bag of D5W or NS, add 100 ml of 10mg/ml ZDV to bag (1 vial ZDV = 20ml). Yield = 1000mg in 250 ml solution Concentration = 4mg/ml. Dose (in ml) = pts. wt. in kg x 1mg/kg/hr divided by 4mg/ml</th>
<th>Rate of Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>125</td>
<td>56.70</td>
<td>113.4</td>
<td>add 113 mg to 100ml D5W or NS</td>
<td>14.2</td>
<td>Run infusion at 14 ml/hr</td>
</tr>
<tr>
<td>130</td>
<td>58.97</td>
<td>117.9</td>
<td>add 118 mg to 100ml D5W or NS</td>
<td>14.7</td>
<td>Run infusion at 15 ml/hr</td>
</tr>
<tr>
<td>135</td>
<td>61.24</td>
<td>122.5</td>
<td>add 123 mg to 100ml D5W or NS</td>
<td>15.3</td>
<td>Run infusion at 15 ml/hr</td>
</tr>
<tr>
<td>140</td>
<td>63.50</td>
<td>127.0</td>
<td>add 127 mg to 100ml D5W or NS</td>
<td>15.9</td>
<td>Run infusion at 16 ml/hr</td>
</tr>
<tr>
<td>145</td>
<td>65.77</td>
<td>131.5</td>
<td>add 132 mg to 100ml D5W or NS</td>
<td>16.4</td>
<td>Run infusion at 16 ml/hr</td>
</tr>
<tr>
<td>150</td>
<td>68.04</td>
<td>136.1</td>
<td>add 136 mg to 100ml D5W or NS</td>
<td>17.0</td>
<td>Run infusion at 17 ml/hr</td>
</tr>
<tr>
<td>155</td>
<td>70.31</td>
<td>140.6</td>
<td>add 141 mg to 100ml D5W or NS</td>
<td>17.6</td>
<td>Run infusion at 18 ml/hr</td>
</tr>
<tr>
<td>160</td>
<td>72.58</td>
<td>145.2</td>
<td>add 145 mg to 100ml D5W or NS</td>
<td>18.1</td>
<td>Run infusion at 18 ml/hr</td>
</tr>
<tr>
<td>165</td>
<td>74.84</td>
<td>149.7</td>
<td>add 150 mg to 100ml D5W or NS</td>
<td>18.7</td>
<td>Run infusion at 19 ml/hr</td>
</tr>
<tr>
<td>170</td>
<td>77.11</td>
<td>154.2</td>
<td>add 154 mg to 100ml D5W or NS</td>
<td>19.3</td>
<td>Run infusion at 19 ml/hr</td>
</tr>
<tr>
<td>175</td>
<td>79.38</td>
<td>158.8</td>
<td>add 159 mg to 100ml D5W or NS</td>
<td>19.8</td>
<td>Run infusion at 20 ml/hr</td>
</tr>
<tr>
<td>180</td>
<td>81.65</td>
<td>163.3</td>
<td>add 163 mg to 100ml D5W or NS</td>
<td>20.4</td>
<td>Run infusion at 20 ml/hr</td>
</tr>
<tr>
<td>185</td>
<td>83.92</td>
<td>167.8</td>
<td>add 168 mg to 100ml D5W or NS</td>
<td>21.0</td>
<td>Run infusion at 21 ml/hr</td>
</tr>
<tr>
<td>190</td>
<td>86.18</td>
<td>172.4</td>
<td>add 172 mg to 100ml D5W or NS</td>
<td>21.5</td>
<td>Run infusion at 22 ml/hr</td>
</tr>
<tr>
<td>195</td>
<td>88.45</td>
<td>176.9</td>
<td>add 177 mg to 100ml D5W or NS</td>
<td>22.1</td>
<td>Run infusion at 22 ml/hr</td>
</tr>
<tr>
<td>200</td>
<td>90.72</td>
<td>181.4</td>
<td>add 181 mg to 100ml D5W or NS</td>
<td>22.7</td>
<td>Run infusion at 23 ml/hr</td>
</tr>
<tr>
<td>205</td>
<td>92.99</td>
<td>186.0</td>
<td>add 186 mg to 100ml D5W or NS</td>
<td>23.2</td>
<td>Run infusion at 23 ml/hr</td>
</tr>
<tr>
<td>210</td>
<td>95.26</td>
<td>190.5</td>
<td>add 191 mg to 100ml D5W or NS</td>
<td>23.8</td>
<td>Run infusion at 24 ml/hr</td>
</tr>
<tr>
<td>215</td>
<td>97.52</td>
<td>195.0</td>
<td>add 195 mg to 100ml D5W or NS</td>
<td>24.4</td>
<td>Run infusion at 24 ml/hr</td>
</tr>
<tr>
<td>220</td>
<td>99.79</td>
<td>199.6</td>
<td>add 200 mg to 100ml D5W or NS</td>
<td>24.9</td>
<td>Run infusion at 25 ml/hr</td>
</tr>
<tr>
<td>225</td>
<td>102.06</td>
<td>204.1</td>
<td>add 204 mg to 100ml D5W or NS</td>
<td>25.5</td>
<td>Run infusion at 26 ml/hr</td>
</tr>
<tr>
<td>230</td>
<td>104.33</td>
<td>208.7</td>
<td>add 209 mg to 100ml D5W or NS</td>
<td>26.1</td>
<td>Run infusion at 26 ml/hr</td>
</tr>
<tr>
<td>235</td>
<td>106.60</td>
<td>213.2</td>
<td>add 213 mg to 100ml D5W or NS</td>
<td>26.6</td>
<td>Run infusion at 27 ml/hr</td>
</tr>
<tr>
<td>240</td>
<td>108.66</td>
<td>217.7</td>
<td>add 216 mg to 100ml D5W or NS</td>
<td>27.2</td>
<td>Run infusion at 27 ml/hr</td>
</tr>
<tr>
<td>245</td>
<td>111.13</td>
<td>222.3</td>
<td>add 222 mg to 100ml D5W or NS</td>
<td>27.8</td>
<td>Run infusion at 28 ml/hr</td>
</tr>
<tr>
<td>250</td>
<td>113.40</td>
<td>226.8</td>
<td>add 227 mg to 100ml D5W or NS</td>
<td>28.3</td>
<td>Run infusion at 28 ml/hr</td>
</tr>
<tr>
<td>255</td>
<td>115.67</td>
<td>231.3</td>
<td>add 231 mg to 100ml D5W or NS</td>
<td>28.9</td>
<td>Run infusion at 29 ml/hr</td>
</tr>
<tr>
<td>260</td>
<td>117.94</td>
<td>235.9</td>
<td>add 236 mg to 100ml D5W or NS</td>
<td>29.5</td>
<td>Run infusion at 30 ml/hr</td>
</tr>
<tr>
<td>265</td>
<td>120.20</td>
<td>240.4</td>
<td>add 240 mg to 100ml D5W or NS</td>
<td>30.1</td>
<td>Run infusion at 30 ml/hr</td>
</tr>
<tr>
<td>270</td>
<td>122.47</td>
<td>244.9</td>
<td>add 245 mg to 100ml D5W or NS</td>
<td>30.6</td>
<td>Run infusion at 31 ml/hr</td>
</tr>
<tr>
<td>275</td>
<td>124.74</td>
<td>249.5</td>
<td>add 250 mg to 100ml D5W or NS</td>
<td>31.2</td>
<td>Run infusion at 31 ml/hr</td>
</tr>
</tbody>
</table>

*Notes: Zidovudine (ZDV) is compatible with Normal Saline (NS) and D5W. When ZDV is mixed with NS or D5W, it is stable for 24 hours at room temperature and 48 hours when refrigerated. For IV use ONLY.
References