



Florida/Caribbean AIDS Education and Training Center

HIV CareLink

A Newsletter for HIV/AIDS Primary Care Providers

ABOUT US

The Florida/Caribbean AIDS Education and Training Center provides state-of-the-art HIV education, consultation, and resource materials to health care providers in Florida, Puerto Rico and the US Virgin Islands.

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Update: Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the U.S.

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It is well known that antiretroviral (ARV) drugs reduce perinatal transmission by multiple mechanisms, including lowering maternal antepartum viral load (VL) and providing infant pre- and post-exposure prophylaxis. To prevent perinatal transmission of HIV a combination of antepartum, intrapartum, and infant ARV prophylaxis is recommended (AI). Key changes made to update the May 24, 2010 version of the perinatal guidelines are summarized in this HIV CareLink. Clinicians are encouraged to view the full guidelines at <http://www.aidsinfo.nih.gov/guidelines/GuidelineDetail.aspx?GuidelineID=9&ClassID=2>.

Findings from International Clinical Trials of Short-Course Antiretroviral Regimens for Prevention of Perinatal Transmission of HIV

- HPTN 046 in breastfeeding infants demonstrated that extending infant nevirapine prophylaxis from 6 weeks to 6 months improved efficacy in reducing postnatal infections.
- NICHD-HPTN 040/PACTG 1043 in formula-feeding infants, demonstrated that when mothers have not received antepartum ARV drugs, combination infant ARV prophylaxis reduces intrapartum transmission more than the standard 6-week infant zidovudine regimen.
- ARV prophylaxis is more effective when given for a longer duration. For this reason, ARV therapy (ART) should be started as soon as possible in women who require treatment of HIV for their own health (AI), and after the first trimester in women who do not require immediate initiation of ART for their own health, although earlier initiation can be considered in these women as well (BIII).

Preconception Counseling and Care for HIV-Infected Women of Childbearing Age

- The guidelines now include recommendations to discuss childbearing intentions with all HIV-infected women of childbearing age on an ongoing basis (AIII) and to provide them with information about available and appropriate contraceptive methods (taking into account their ART regimen) to reduce the likelihood of unintended pregnancy (AI).

- A new sub-section on reproductive options for HIV-concordant and serodiscordant couples has been added. To view the Panel's recommendations visit: <http://aidsinfo.nih.gov/contentfiles/PerinatalGL.pdf#page=36>
- A table, providing useful and current information on drug interactions between hormonal contraceptives and ARV drugs has been added to the Guidelines. To view Table 4 visit: <http://aidsinfo.nih.gov/contentfiles/PerinatalGL.pdf#page=33>

Antepartum Care (New Recommendations)

- All pregnant HIV-infected women should receive a combination antepartum ART regimen to prevent perinatal transmission regardless of plasma HIV VL or CD4 cell count (AI). Three-drug combination ART is recommended both for women who require therapy for their own health (AI) and for the prevention of perinatal transmission in those who do not meet treatment criteria for therapy. (AII).
- When HIV is diagnosed late in pregnancy, ART or prophylaxis should be started immediately without waiting for the results of resistance testing (BIII).
- Recommendations for continuation of ART for maternal therapeutic indications after delivery are the same as for non-pregnant individuals. The risks and benefits of continuing versus discontinuing ART postpartum should be discussed with each patient so they can make an educated decision about postpartum ARV use (AIII).

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National Clinicians' Consultation Hotline:

1-800-933-3413

HIV-Infected Pregnant Women Who Have Never Received Antiretroviral Drugs (Antiretroviral Naïve)

- This section includes an expanded discussion of new data suggesting early and sustained control of HIV viral replication is associated with decreased transmission in women who have undetectable viral load at delivery. This data favors initiation of ART as early in pregnancy as possible for all women.

HIV/Hepatitis B Virus (HBV) Coinfection

- New recommendations for treatment in this special situation. Now, all pregnant women with HIV/HBV coinfection should receive combination ART. This regimen needs to include a dual nucleoside reverse transcriptase inhibitor (NRTI)/nucleotide analogue reverse transcriptase inhibitor (NtRTI) backbone with two agents active against both HIV and HBV (AII). The preferred dual NRTI/NtRTI backbone for combination antepartum ART in HIV/HBV-coinfected pregnant women is the same as recommended for non-pregnant patients [i.e. tenofovir plus (lamivudine or emtricitabine)] (AI).

New Section on HIV-2 Infection and Pregnancy

- HIV-2 infection should be suspected in pregnant women who are from (or have partners who are from) countries in which HIV-2 is endemic (e.g. Angola, Mozambique, West Africa and parts of India). It also has to be suspected in women who are HIV antibody positive on an initial enzyme-linked immunoassay screening test, and who have repeatedly indeterminate results on HIV-1 Western blot and an HIV-1 RNA VL at or below the limit of detection (BII).
- Combination ART with two NRTIs and a boosted protease inhibitor (PI) (zidovudine/lamivudine + lopinavir/ritonavir preferred) is recommended for HIV-2-infected pregnant women who require treatment for their own health (AIII). Tenofovir plus (lamivudine or emtricitabine) plus lopinavir/ritonavir is an alternative (BIII).
- Optimal prophylactic regimens have not been defined for HIV-2-infected pregnant women who do not meet treatment criteria. In those situations, the following approaches are recommended: boosted PI-based regimen (i.e. two NRTIs plus lopinavir/ritonavir) for prophylaxis, with the drugs stopped postpartum (BIII); or zidovudine prophylaxis alone during pregnancy and intrapartum (BIII).
- Since non-nucleoside reverse transcriptase inhibitors (NNRTIs) and enfuvirtide are not active against HIV-2, they should not be used for treatment or prophylaxis (AIII).
- All infants born to HIV-2-infected mothers should receive the standard 6-week zidovudine prophylactic regimen (BIII). Breastfeeding is not recommended in the U.S. for infants of HIV-2-infected mothers (AIII).

Acute HIV Infection During Pregnancy (New Section)

- If acute retroviral syndrome is suspected during pregnancy or the breastfeeding period, both a plasma HIV RNA PCR and an HIV antibody test should be obtained (AII).
- Repeat HIV antibody testing in the third trimester is recommended for: women with initial negative HIV antibody tests who are known to be at risk of HIV; women who are receiving care in facilities that have an HIV incidence in pregnant women of at least 1 per 1,000 per year; women who are incarcerated, or reside in jurisdictions with increased rates of HIV infection (AII).
- For all pregnant women with acute or recent HIV infection, the same guidelines for treatment of HIV infection apply. Combination ART should be started as soon as possible to prevent mother-to-child transmission (AI).
- A ritonavir-boosted PI-based regimen should be initiated, since clinically significant resistance to PIs is less common than resistance to NNRTIs in ART individuals in general (AIII).
- Genotypic resistance testing should be performed simultaneously with initiation of ART, and if necessary, the ARV regimen should be adjusted when results become available (AIII).

Intrapartum Care

- Based on the results of the NICHD-HPTN040/P1043 clinical trial, the Panel no longer recommends intrapartum single-dose nevirapine for HIV-infected women in labor who have not received antepartum drugs. For these women, intravenous zidovudine is recommended during labor and combination ARV prophylaxis for 6 weeks is recommended for their infants (AII).

Post-partum Management (New Recommendations)

- Discussion of contraception should be included in the course of postpartum care (AIII).
- Decisions about continuing ART after delivery should include current recommendations for initiation of ART, current and nadir CD4 cell counts and trajectory, HIV RNA VL, adherence issues, whether the woman has an HIV-uninfected sexual partner, and patient preference (AIII).
- Because the immediate postpartum period poses unique challenges to adherence, arrangements for new or continued supportive services should be made prior to hospital discharge for women who are going to continue ART postpartum (AII).



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Infant Antiretroviral Prophylaxis

- Based on the results of the NICHD-HPTN 040/PACTG 1043 trial, the new recommendations for infant antiretroviral prophylaxis are:
 - A combination ARV drug regimen, begun as soon as possible after birth, should be given to infants born to HIV-infected women who have not received antepartum ARV drugs (AI). A randomized, controlled trial showed that 6 weeks of zidovudine in combination with 3 doses of nevirapine given during the first week of life, (at birth, 48 hours later, and 96 hours after the second dose) was shown to be as effective, but less toxic than 6 weeks of zidovudine combined with nelfinavir and lamivudine given over 2 weeks.
- **IMPORTANT CHANGE:** The recommended dose of zidovudine for post-exposure prophylaxis in full-term neonates is now 4 mg/kg body weight orally twice daily for the first 6 weeks of life, beginning as soon as possible after birth and preferably within 6–12 hours of delivery. This should make adherence easier for the families than the previous dosing every 6 hours. This dosing change is based on the results of several clinical trials and also the World Health Organization recommendations.

ARV-related Complications/Side Effects (Updates)

- Although a possible small increased risk of preterm birth in pregnant women receiving PI-based combination ART exists, the clear benefits for both the women's health and the prevention of mother-to-child transmission outweigh the risk. As such, PIs should not be avoided for fear of altering pregnancy outcome (AII).
- Nevirapine-based regimens should be started in women with CD4 counts >250 cells/mm³ only if the benefits clearly outweigh the risks because of the drug's potential for causing hepatic toxicity or hypersensitivity reaction (AII). Women who become pregnant while receiving nevirapine-containing regimens, and who are tolerating the regimen well, can continue with the therapy regardless of CD4 count (AII).
- Due to reports of lactic acidosis and maternal/neonatal mortality with prolonged use in pregnancy, the combination of stavudine and didanosine should not be prescribed during pregnancy (AII).
- In uninfected children who were exposed to ARVs perinatally and present with severe clinical findings of unknown etiology, particularly neurologic findings, mitochondrial dysfunction should be considered (AII).
- For any child with *in utero* exposure to ARVs, long-term clinical follow-up is recommended (AIII).
- Lopinavir/ritonavir should not be administered to neonates before a postmenstrual age (first day of the mother's last menstrual period to birth, plus the time elapsed since birth) of 42 weeks and a postnatal age of at least 14 days. This is based on reports of cardiac toxicity (e.g. atrioventricular block, bradycardia, and

cardiomyopathy), lactic acidosis, acute renal failure, central nervous system depression, and respiratory complications leading to death, predominantly in preterm neonates. The Food and Drug Administration issued a warning earlier this year and now it is included in the guidelines.

The National Perinatal HIV Hotline (1-888-448-8765) provides free clinical consultation to providers caring for HIV-infected pregnant women and their infants.

References

1. Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission. Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States. Sep. 14, 2011; pp 1-207. Available at <http://aidsinfo.nih.gov/contentfiles/PerinatalGL.pdf>. Accessed (9/19/2011).



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