



Updated Guidelines for Managing HIV in Pregnancy from the USPHS Task Force

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Updated Guidelines for Managing HIV in Pregnancy from the USPHS Task Force

John G. Bartlett, MD, and Jean R. Anderson, MD

The Public Health Service Task Force's recent revision of "Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Intervention to Reduce Perinatal HIV-1 Transmission in the United States" demonstrates substantial changes in recommendations, reflecting new information on viral load and perinatal transmission, choice of antiretroviral drugs, preconception counseling, and the role of Cesarean section. The major changes are summarized below. (The full text of these guidelines is available at: <http://www.hivatis.org/> and on the Johns Hopkins AIDS Service website: <http://www.hopkins-aids.edu/>.)

WHEN TO TREAT

All pregnant women with HIV infection should be treated with antiretroviral therapy regardless of CD4 cell count or viral load. Perinatal transmission directly correlates with viral load. Furthermore, a recent meta-analysis of seven European and US prospective studies examining mother-to-child transmission with maternal viral load <1000 c/mL found that risk of transmission was lowered from 9.8% in untreated women to 1% in women treated with antiretroviral therapy (generally AZT alone). The recommendation to treat all pregnant women is a clear departure from the most current DHHS guidelines for non-pregnant adults and adolescents, which suggest deferral of treatment until the CD4 count drops below 350 cells/mm³ and/or viral load rises above 30,000–55,000 c/mL. The reason for this difference is the additional goal in each pregnancy to reduce perinatal transmission. In antiretroviral-naïve women, initiation of therapy may be delayed until after the first trimester due to theoretical concerns regarding risk of adverse effects with drug administration during the period of organ formation.

AGENT SELECTION

The recommendation is to include AZT as part of the overall antiretroviral regimen using each of the three components of the 076 protocol: antepartum, intrapartum, neonatal. This drug appears to confer benefit in reducing perinatal transmission even when it has little or no effect on viral load and even in the presence of AZT-resistant virus. With viral load >1000 c/mL, a standard HAART regimen in addition to the 076 regimen is recommended. When the pregnant woman cannot take AZT because of side effects or toxicity, the intrapartum and newborn components of the 076 protocol should still be utilized. With regard to other drugs, the following points are to be emphasized:

- The combination of ddI and d4T should be prescribed with caution during pregnancy and avoided if possible due to reports of three deaths in pregnant women who were receiving this regimen and developed lactic acidosis.
- The oral solution of amprenavir contains large quantities of propylene glycol, which cannot be metabolized in pregnancy. The capsule form of amprenavir is not problematic.
- Hydroxyurea should be strictly avoided during pregnancy due to teratogenicity.
- Efavirenz should be avoided in pregnancy,

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especially during the first trimester, because of teratogenic effects in a primate model. It should be noted that this drug has not been studied in human pregnancies and other antiretroviral drugs have not been tested in a primate model. The safety of using efavirenz after the first trimester when major organ formation is complete is unknown but may be a consideration in women with limited therapeutic options.

- AZT and d4T should not be used together in any HIV-infected patient due to pharmacologic antagonism.
- Nevirapine is included in two of four recommended options for untreated women who present in labor. This drug may be given using an oral dose of 200 mg p.o. at onset of labor plus a single dose of 2 mg/kg to the infant at 48–72 hours. An alternative is to combine this regimen with AZT according to the ACTG 076 protocol for intrapartum and postpartum management. Recently reported results of the PACTG 316 study found no additional benefit to adding this regimen to an already existing standard antiretroviral regimen in terms of perinatal prophylaxis.

PRECONCEPTION COUNSELING

As more women with HIV are considering pregnancy because of the therapeutic advances in HIV care as well as dramatic reductions in perinatal transmission, it is important to give appropriate preconception care and counseling to HIV-infected women of childbearing age. Recommended components of preconception counseling include:

- Selection of effective and appropriate contraceptive methods to reduce the likelihood of unintended pregnancy.
- Counseling about perinatal transmission risks and prevention, and potential effects of HIV or treatment on pregnancy course and outcomes.
- Initiation or modification of antiretroviral therapy prior to conception in order to: avoid agents with potential fetal toxicity; choose agents effective in reducing risk of perinatal transmission; attain a stable and maximally suppressed maternal viral load; and evaluate and manage therapy-associated side effects which can adversely affect maternal-fetal health outcomes.

- Give indicated immunizations and/or OI prophylaxis.
- Optimize maternal nutritional status.
- Screen for psychological and substance abuse disorders.
- Implement other standard components of preconception evaluation and management.

CESAREAN SECTION

Scheduled C-section should be considered for women who have viral loads >1000 c/mL at 36 weeks. The recommended timing for this intervention is 38 weeks gestation. Current studies show no benefit to this approach if C-section is performed after the onset of labor or ruptured membranes. The decision for this intervention requires full informed consent by the mother in terms of risks and benefits. The major benefit is a significant reduction in the probability of perinatal transmission in these women. Although data are limited, it is thought to be unlikely that C-section has additional benefit in women who are on antiretroviral therapy and have suppression of viral load to below 1000 c/mL. Although data have not conclusively shown an increase in post-Cesarean morbidity in HIV-infected women compared to uninfected women, a recent study found a 3–4 fold increase in risk of fever, UTI, or any postpartum morbidity in HIV-infected women having a C-section compared to those with spontaneous vaginal delivery [Read, et al., *JAIDS* 2001;26:236].

ADDITIONAL CONSIDERATIONS

A few other principles are worth mentioning as applied to pregnancy and HIV infection. First, some authorities feel that antiretroviral therapy should be suspended during the first trimester in women who enter pregnancy on therapy based on concerns for infant exposure during the period of organ development. This is a theoretical concern that must be addressed in the context of risk/benefit on an individual basis. Many women have difficulty tolerating certain antiretroviral agents, especially those that have gastrointestinal side effects, since these may be exacerbated by the nausea and vomiting common in early pregnancy. If there is difficulty maintaining adherence or concerns about adequate absorption because of these problems, therapy may need to be temporarily suspended

and, if so, all drugs should be stopped and later restarted simultaneously. An alternative would be a change in regimen to one better tolerated but equally effective. Finally, patient monitoring of CD4 count, viral load, and indications for resistance testing are the same for pregnant and for non-pregnant women. Some adverse drug reactions (e.g., hyperglycemia) may be more common in pregnancy because of interaction with pregnancy-related physiologic changes, or may be overlooked because of similarity to symptoms common in pregnancy, or may be confused with

pregnancy-specific pathologies (such as lactic acidosis and fatty liver of pregnancy). The clinician caring for the pregnant woman with HIV should maintain a high index of suspicion for the possibility of adverse drug reactions and should monitor as indicated. The ultimate goals of therapy in pregnancy are to prevent mother-to-child transmission and to reduce viral load in the mother as much as possible for as long as possible while retaining reasonable therapeutic options for the future and preserving quality of life as much as possible.