



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

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Introduction (Last updated July 31, 2012; last reviewed July 31, 2012)

Recommendations regarding HIV screening and treatment of pregnant women and prophylaxis for perinatal transmission of HIV have evolved considerably in the United States over the last 25 years, reflecting changes in the epidemic and the science of prevention.^{1,2} With the implementation of recommendations for universal prenatal HIV counseling and testing, antiretroviral (ARV) prophylaxis, scheduled cesarean delivery, and avoidance of breastfeeding, the rate of perinatal transmission of HIV has dramatically diminished to less than 2% in the United States and Europe.³⁻⁶

These guidelines update the **September 14, 2011**, 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. The Department of Health and Human Services Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission, a working group of the Office of AIDS Research Advisory Council, develops these guidelines. The guidelines provide health care providers with information for discussion with HIV-infected pregnant women to enable the patient/provider team to make informed decisions regarding the use of ARV drugs during pregnancy and use of scheduled cesarean delivery to reduce perinatal transmission of HIV. The recommendations in the guidelines are accompanied by discussion of various circumstances that commonly occur in clinical practice and the factors influencing treatment considerations. The Panel recognizes that strategies to prevent perinatal transmission and concepts related to management of HIV disease in pregnant women are rapidly evolving and will consider new evidence and adjust recommendations accordingly. The updated guidelines are available from the AIDSinfo website (<http://aidsinfo.nih.gov>).

Health care providers considering the use of ARV agents for HIV-infected women during pregnancy must take into account two separate but related issues:

1. ARV treatment of maternal HIV infection and
2. ARV chemoprophylaxis to reduce the risk of perinatal transmission of HIV.

The benefits of ARV drugs for a pregnant woman must be weighed against the risks of adverse events to the woman, fetus, and newborn. Combination drug regimens are considered the standard of care both for treatment of HIV infection and for prevention of perinatal transmission of HIV.^{2,7} After provider counseling and discussion on ARV drug use during pregnancy, a pregnant woman's informed choice on whether to take ARV drugs for her treatment, for prevention of mother-to-child transmission, and/or to follow other medical recommendations intended to reduce perinatal transmission of HIV should be respected. Coercive and punitive policies are potentially counterproductive; they may undermine provider-patient trust and could discourage women from seeking prenatal care and adopting health care behaviors that optimize fetal and neonatal well-being.

The current guidelines have been structured to reflect the management of an individual mother-child pair and are organized into a brief discussion of preconception care followed by principles for management of a woman and her infant during the antepartum, intrapartum, and postpartum periods. Although perinatal transmission of HIV occurs worldwide, these recommendations have been developed for use in the United States. Alternative strategies may be appropriate in other countries. Policies and practices in other countries regarding the use of ARV drugs for reduction of perinatal transmission of HIV may differ from the recommendations in these guidelines and will depend on local considerations, including availability and cost of ARV drugs, accessibility of facilities for safe intravenous infusions during labor, and local recommendations regarding breastfeeding by HIV-infected women.

Guidelines Development Process

Table 1. Outline of the Guidelines Development Process

Topic	Comment
Goal of the guidelines	Provide guidance to HIV care practitioners on the optimal use of antiretroviral (ARV) agents in pregnant women for treatment of HIV infection and for prevention of mother-to-child transmission (PMTCT) of HIV in the United States.
Panel members	The Panel is composed of approximately 30 voting members who have expertise in management of pregnant HIV-infected women (such as training in either obstetrics/gynecology or women's health) and interventions for PMTCT (such as specialized training in pediatric HIV infection) as well as community representatives with knowledge of HIV infection in pregnant women and interventions for PMTCT. The U.S. government representatives, appointed by their agencies, include at least 1 representative from each of the following Department of Health and Human Services agencies: the Centers for Disease Control and Prevention, the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), and the National Institutes of Health (NIH). Members who do not represent U.S. government agencies are selected by Panel members after an open announcement to call for nominations. Each member serves on the Panel for a 3-year period, with an option for reappointment. A list of all Panel members can be found in the Panel Roster .
Financial disclosures	All members of the Panel submit a written financial disclosure annually reporting any association with manufacturers of ARV drugs or diagnostics used for management of HIV infections. A list of the latest disclosures is available on the <i>AIDSinfo</i> website (http://aidsinfo.nih.gov).
Users of the guidelines	Providers of care to HIV-infected pregnant women and to HIV-exposed infants
Developer	Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission—a working group of OARAC
Funding source	Office of AIDS Research, NIH
Evidence for recommendations	The recommendations in these guidelines are generally based on studies published in peer-reviewed journals. On some occasions, particularly when new information may affect patient safety, unpublished data presented at major conferences or prepared by the FDA and/or manufacturers as warnings to the public may be used as evidence to revise the guidelines.
Recommendation grading	See Table 2 .
Method of synthesizing data	Each section of the guidelines is assigned to a small group of Panel members with expertise in the area of interest. A structured literature search is conducted by staff from the HIV/AIDS National Resource Center at the Francois-Xavier Bagnoud Center (through funding from HRSA) and provided to the Panel working group. The members review and synthesize the available data and propose recommendations to the entire Panel. The Panel discusses and votes on all proposals during monthly teleconferences. Proposals receiving endorsement from a consensus of members are included in the guidelines as official Panel recommendations.
Other guidelines	These guidelines focus on HIV-infected pregnant women and their infants. Other guidelines outline the use of ARV agents in non-pregnant HIV-infected adults and adolescents, HIV-infected children, and people who experience occupational or nonoccupational exposure to HIV. The guidelines described are also available on the <i>AIDSinfo</i> website (http://aidsinfo.nih.gov). Preconception management for non-pregnant women of reproductive age is briefly discussed in this document. However, for more detailed discussion on issues of treatment of non-pregnant adults, the Working Group defers to the designated expertise offered by Panels that have developed those guidelines.

Guidelines Development Process

Table 1. Outline of the Guidelines Development Process, cont'd

Topic	Comment
Update plan	The Panel meets monthly by teleconference to review data that may warrant modification of the guidelines. Updates may be prompted by new drug approvals (or new indications, new dosing formulations, or changes in dosing frequency), significant new safety or efficacy data, or other information that may have a significant impact on the clinical care of patients. In the event of significant new data that may affect patient safety, the Panel may issue a warning announcement and accompanying recommendations on the <i>AIDSinfo</i> website until the guidelines can be updated with appropriate changes. Updated guidelines are available at the <i>AIDSinfo</i> website (http://aidsinfo.nih.gov).
Public comments	A 2-week public comment period follows release of the updated guidelines on the <i>AIDSinfo</i> website. The Panel reviews comments received to determine whether additional revisions to the guidelines are indicated. The public may also submit comments to the Panel at any time at contactus@aidsinfo.nih.gov .

Basis for Recommendations

Recommendations in these guidelines are based on scientific evidence and expert opinion. Each recommended statement is rated with a letter of **A**, **B**, or **C** that represents the strength of the recommendation and with a numeral **I**, **II**, or **III**, according to the quality of evidence.

Table 2. Rating Scheme for Recommendations

Strength of Recommendation	Quality of Evidence for Recommendation
A: Strong recommendation for the statement	I: One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
B: Moderate recommendation for the statement	II: One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes
C: Optional recommendation for the statement	III: Expert opinion

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