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 November 14, 2017; last reviewed November 14, 2017)

Recommendations regarding HIV screening and treatment of pregnant women and prophylaxis for perinatal transmission of HIV have evolved considerably in the United States since the mid-1990s, reflecting changes in both the epidemic and also in the science of prevention and treatment. With the implementation of recommendations for universal prenatal HIV counseling and testing, maternal antiretroviral treatment (ART) for all pregnant women living with HIV, scheduled cesarean delivery for women with HIV RNA >1,000 near delivery, infant antiretroviral (ARV) prophylaxis, and avoidance of breastfeeding, the rate of perinatal transmission of HIV has dramatically diminished to 2% or less in the United States and Europe.[1,2] In response to this success, the Centers for Disease Control and Prevention has developed a goal of eliminating perinatal HIV transmission in the United States, defined as reducing perinatal transmission to an incidence of <1 infection per 100,000 live births and to a rate of <1% among HIV-exposed infants.[3]

It is estimated that 8,700 women living with HIV (95% CI, 8,400–8,800) give birth annually in the United States.[4] A focus on appropriate overall medical care for women living with HIV is the best way to prevent HIV infection of infants, including comprehensive reproductive health, family planning and preconception care services, optimization of HIV treatment, and maintenance of care for women living with HIV between pregnancies. A critical component of prevention of perinatal HIV transmission is ensuring the use of ART to maximally suppress viral replication as early as possible during pregnancy or, ideally, prior to conception.

These Guidelines update the October 2016 Perinatal Guidelines. The Department of Health and Human Services Panel on Treatment of Pregnant Women Living with HIV and Prevention of Perinatal Transmission (the Panel), 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 pregnant women living with HIV infection to enable collaborative, informed decision-making regarding the use of ARV drugs during pregnancy, use of scheduled cesarean delivery to reduce perinatal transmission of HIV, and decision-making around use of ARV drugs for prophylaxis of infants exposed to HIV. The recommendations in these Guidelines are accompanied by discussion of various circumstances that commonly occur in clinical practice and the factors that influence treatment considerations. The Panel recognizes that strategies to prevent perinatal transmission and concepts related to management of HIV in pregnant women are rapidly evolving and will consider new evidence and adjust recommendations accordingly. The updated guidelines are available from the AIDS*info* website (http://aidsinfo.nih.gov). The National Perinatal HIV Hotline (1-888-448-8765) is a federally funded service providing free clinical consultation to providers caring for women living with or at risk for HIV and their children, and serves as a resource for obtaining expert consultation for individual cases.

The Panel supports recommendations to ensure that women receive the full benefit of ART for their own health and for prevention of perinatal transmission. However, the Panel recognizes the right of women to make informed choices about treatment during pregnancy, even when their choices might differ from a health care provider's recommendations.

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 managing the care 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.

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 living with HIV for treatment of HIV infection and for prevention of perinatal transmission of HIV and management of HIV-exposed infants in the United States.
Panel Members	The Panel is composed of approximately 30 voting members who have expertise in managing the care of pregnant women living with HIV (e.g., training in obstetrics/gynecology, infectious diseases, or women's health), pharmacology of ARV drugs during pregnancy, and interventions for prevention of perinatal transmission (e.g., specialized training in pediatric HIV infection), as well as community representatives with knowledge of HIV infection in pregnant women and interventions for prevention of perinatal transmission. The U.S. government representatives, appointed by their agencies, include at least one 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 re-appointment. The Panel may also include liaison members from the Perinatal HIV Hotline, the American Academy of Pediatrics' Committee on Pediatric AIDS, and the American College of Obstetricians and Gynecologists. A list of all Panel members can be found on Page IV of the guidelines.
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 AIDS*info* website (http://aidsinfo.nih.gov).
Users of the Guidelines	Providers of care to HIV-infected pregnant women and to HIV-exposed infants
Developer	The Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission—a working group of the Office of AIDS Research Advisory Council (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 a technical assistance consultant 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 all proposals during monthly teleconferences. Proposals are modified based on Panel discussion and then distributed, with ballots, to all Panel members for concurrence and additional comments. If there are substantive comments or votes against approval, the recommended changes and areas of disagreement are brought back to the full Panel (via email or teleconference) for additional review, discussion, and further modification to reach a final version acceptable to all Panel members. The recommendations in these final versions represent endorsement from a consensus of members and are included in the guidelines as official Panel recommendations.
Other Guidelines	These Guidelines focus on pregnant women living with HIV and their infants. Other Guidelines (all available on the AIDS*info* website http://www.aidsinfo.nih.gov) outline the use of ARV agents in non-pregnant adults and adolescents with HIV; use of ARV agents in infants and children with HIV; treatment and prevention of opportunistic infections (OIs) in adults and adolescents with HIV, including pregnant women; treatment and prevention of OIs in children exposed to HIV or with HIV infection; and treatment of people who experience occupational or non-occupational exposure to HIV. 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, and/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 AIDS*info* website until the guidelines can be updated with appropriate changes. Updated guidelines are available on the AIDS*info* website (http://www.aidsinfo.nih.gov).
Public Comments	A 2-week public comment period follows release of the updated guidelines on the AIDS*info* 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** that represents the quality of evidence.

Table 2. Rating Scheme for Recommendations

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

References

1. Townsend CL, Byrne L, Cortina-Borja M, et al. Earlier initiation of ART and further decline in mother-to-child HIV transmission rates, 2000-2011. *AIDS*. 2014;28(7):1049-1057. Available at http://www.ncbi.nlm.nih.gov/pubmed/24566097.
2. Centers for Disease Control and Prevention. Enhanced perinatal surveillance–15 areas, 2005-2008. *HIV Surveillance Supplemental Report 2011*. 2011;16 (no. 2). Available at http://www.cdc.gov/hiv/topics/surveillance/resources/reports.
3. Nesheim S, Taylor A, Lampe MA, et al. A framework for elimination of perinatal transmission of HIV in the United States. *Pediatrics*. 2012;130(4):738-744. Available at http://www.ncbi.nlm.nih.gov/pubmed/22945404.
4. Whitmore SK, Zhang X, Taylor AW, Blair JM. Estimated number of infants born to HIV-infected women in the United States and five dependent areas, 2006. *J Acquir Immune Defic Syndr*. 2011;57(3):218-222. Available at http://www.ncbi.nlm.nih.gov/pubmed/21372725.