

What's New in the Guidelines

(Last updated February 10, 2021; last reviewed February 10, 2021)

Text and references throughout the guidelines were updated to include new data and publications where relevant. These changes are highlighted in yellow in the PDF version of the guidelines. Major section revisions are summarized below.

February 10, 2021

The Panel has begun to make revisions in language to be more inclusive for the care of transgender and non-binary people who are pregnant or trying to conceive. Revisions are limited to a few sections at present, but this is an effort that will continue in future updates.

Recommendations for the Use of Antiretroviral Drugs During Pregnancy

- The Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission (the Panel) recommends dolutegravir (DTG) as a *Preferred* antiretroviral (ARV) drug throughout pregnancy and now also recommends DTG as a *Preferred* ARV for women who are trying to conceive. This decision was based on updated data showing that the increased risk of neural tube defects (NTDs) associated with the use of DTG is very small and the advantages of DTG which include once-daily dosing, being generally well tolerated, and producing rapid, durable viral load suppression, which is important for maternal health and the prevention of perinatal HIV transmission.
- With this change, the Panel has removed DTG-specific recommendations, but added content about balancing the risks and benefits of specific ARV drugs in the face of limited data. The Panel continues to emphasize the importance of counseling and informed decision making regarding the use of DTG and all ARV drugs during pregnancy and for people who are trying to conceive and has revised the Counseling Guide in [Appendix C](#), accordingly.
- Lopinavir/ritonavir, formerly classified as an *Alternative* ARV is now *Not Recommended Except in Special Circumstances* based on data about increased risks of preterm delivery and small for gestational age infants (see [Antiretroviral Drug Regimens and Maternal and Neonatal Outcome](#)) as well as requirements for twice daily dosing and potential nausea and vomiting.
- The Panel recommends [tenofovir alafenamide](#) (TAF) as an *Alternative* nucleoside reverse transcriptase inhibitor for ARV therapy regimens now that additional data about the use and safety of TAF in pregnancy has become available.
- The Panel has revised language about its recommendations about cobicistat containing ARV regimens that pose a risk for low drug levels and viral rebound in the second and third trimesters to point out that some health care providers and their patients may choose to continue with frequent viral load monitoring, rather than switching to a new regimen.
- Fostemsavir, a new ARV, has been classified as *Insufficient Data* for use in pregnancy.
- Revisions have been made to the sections listed below, and those published in December 2020, to incorporate the Panel's updated recommendations about ARV drugs during pregnancy and for women who are trying to conceive.
 - [Pregnant People with HIV Who Have Never Received Antiretroviral Drugs \(Antiretroviral Naive\)](#)
 - [Table 4. What to Start: Initial Combination Regimens for Antiretroviral-Naive Pregnant Women](#)
 - [Pregnant Women with HIV Who Are Currently Receiving Antiretroviral Therapy](#)
 - [Acute HIV](#)
 - [Appendix C: Antiretroviral Counseling Guide for Health Care Providers](#)

December 29, 2020

Introduction

- The Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission (the Panel) has added a new guidelines section, [HIV Pre-Exposure Prophylaxis \(PrEP\) to](#)

Reduce the Risk of Acquiring HIV During Periconception, Antepartum, and Postpartum Periods.

- The Panel has begun to make revisions in language and content in the guidelines to address the care of transgender and non-binary people who are pregnant or trying to conceive, an effort that will continue in future updates.

Maternal HIV Testing and Identification of Perinatal HIV Exposure

- Bulleted recommendations have been updated to point out that repeat HIV testing is recommended for pregnant women with a sexually transmitted infection or with signs and symptoms of acute HIV infection (**AIII**) and that expedited HIV testing during labor is recommended for those who are at increased risk of HIV infection and were not retested in the third trimester (**AIII**).

HIV Pre-Exposure Prophylaxis (PrEP) to Reduce the Risk of Acquiring HIV During Periconception, Antepartum, and Postpartum Periods

- This new section provides Panel recommendations and summarizes available evidence about the rationale for PrEP and its use and safety in individuals who are trying to conceive or are pregnant, postpartum, or breastfeeding.
- The Panel recommends that health care providers offer and promote oral combination tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) PrEP to individuals who are at risk for HIV and are trying to conceive or are pregnant, postpartum, or breastfeeding (**AII**). Indications for PrEP include any risk factors for acquiring HIV, such as condomless sex with a partner with HIV whose HIV-RNA level is detectable or unknown, recent sexually transmitted infection, or injection drug use. Because risk factors may be underreported, those who report feeling at risk for HIV acquisition should be counseled on the benefits and risks of and be offered PrEP.
- Providers should counsel individuals about the benefits (**AI**) and risks (**AII**) of PrEP for their health and their infants and about the importance of daily adherence to oral PrEP in preventing HIV acquisition (**AI**).
- The section includes recommendations for PrEP initiation and follow-up with links to the [Centers for Disease Control and Prevention HIV Pre-Exposure Prophylaxis Guidelines](#) for additional guidance.
- Health care providers are strongly encouraged to register patients who become pregnant while receiving PrEP with the [Antiretroviral Pregnancy Registry](#).

Reproductive Options for Couples When One or Both Partners Have HIV

- Content about PrEP has been shortened and is now linked to the new section, [HIV Pre-Exposure Prophylaxis \(PrEP\) to Reduce the Risk of Acquiring HIV During Periconception, Antepartum, and Postpartum Periods](#).

General Principles Regarding Use of Antiretroviral Drugs During Pregnancy

- Prenatal care for people with HIV should include assessment of the patient's self-affirmed gender identify, preferred pronouns, use of gender-affirming hormonal therapy, and potential interactions with ARV (see [Transgender People with HIV](#)).
- It is important to be aware that COVID-19 may increase the risk of depression, substance use, and intimate partner violence at a time when the frequency of in-person health care services has decreased (see [Interim Guidance for COVID-19 and Persons with HIV](#)).

Teratogenicity

- Bulleted recommendations have been revised to reflect additional data and updated Panel recommendations for dolutegravir, which is now a *Preferred* antiretroviral drug for people who are trying to conceive, rather than an *Alternative*.

Antiretroviral Drug Regimens and Maternal and Neonatal Outcomes

- The Panel has added a summary of key points about the outcomes of preterm delivery, low birth weight and small-for-gestational-age infants, stillbirth, and hypertensive disorders of pregnancy.

Monitoring of the Woman and Fetus During Pregnancy

- Information in the bulleted recommendations and the text is now summarized in a new table, Table 6. HIV-Related Laboratory Monitoring Schedule for Pregnant Women with HIV.

Antiretroviral Drug Resistance and Resistance Testing in Pregnancy

- The following guidance from the text has been added as a bulleted recommendation: Phenotypic resistance testing is indicated for treatment-experienced persons on failing regimens who are thought to have multidrug resistance (**BIII**).

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Hepatitis B Virus/HIV Coinfection

- Tenofovir alafenamide (TAF) now is included as an option for the treatment of hepatitis B virus and HIV coinfection based on the Panel's updated recommendation of TAF as an *Alternative* non-nucleoside reverse transcriptase inhibitor for the people with HIV who are pregnant or are trying to conceive.

Hepatitis C Virus/HIV Coinfection

- Patients with hepatitis C virus (HCV) should be strongly considered for HCV treatment with direct-acting antiviral agents postpartum (**AI**).
- The Panel recommends that for patients who have tested positive for HCV, their HCV RNA should be evaluated after delivery to assess for spontaneous clearance of HCV infection, particularly as they are being considered for initiation of HCV therapy postpartum (**BII**).

Intrapartum Care for Women with HIV

- The former sections on Intrapartum Antiretroviral Therapy/Prophylaxis, Transmission and Mode of Delivery, and Other Intrapartum Management Considerations have been combined into a single section, and Table 7, Intrapartum Care and Recommended Interventions to Prevent Perinatal HIV Transmission for Women with HIV Based on Maternal HIV RNA at the Time of Delivery, has been added to provide easy access to information.
- In the new combined section, some of the Panel's bulleted recommendations have been reorganized according to maternal HIV RNA near the time of delivery, which is defined as ≥ 34 –36 weeks gestation or 4–6 weeks before delivery.
- The Panel has made some additions to the bulleted recommendations to highlight important content from the text clarification. For example, labor should not be induced to prevent perinatal HIV transmission.

Postpartum Follow-Up of Women With HIV

- The Panel recommends that women who desire to breastfeed should receive evidence-based counseling on infant feeding options (**AIII**) (see [Counseling and Managing Women with HIV in the United States Who Desire to Breastfeed](#)).

Antiretroviral Management of Newborns with Perinatal HIV Exposure of HIV Infection

- In describing infants at high or low risk of perinatal acquisition of HIV and maternal risk factors for perinatal HIV transmission, viral suppression is defined as HIV RNA < 50 copies/mL.
- Information about recommended antiretroviral drugs for infants with perinatal exposure to HIV-2 infection is available in Table 9 and [HIV-2 Infection and Pregnancy](#).
- Table 9 has been updated to include dosing of dolutegravir dispersible tablets for oral suspension for HIV therapy, which can replace lopinavir/ritonavir, nevirapine, or raltegravir in infants at least 4 weeks of age and weighing at least 3 kg.

- Information about the two-drug regimen of nevirapine and zidovudine used in NICHD-HPTN 040/PACTG 1043 has been removed from Table 9 but is available in the text (see Two-Drug Antiretroviral Prophylaxis).
- Maraviroc (MVC) was approved recently for infants weighing ≥ 2 kg and may provide an additional treatment option for newborns of women carrying multidrug resistant HIV-1 that remains CCR5-trophic. However, the lack of data about MVC as prophylaxis or treatment in infants weighing < 10 kg and the risk of drug interactions will limit its role for routine use in neonates.

Diagnosis of HIV Infection in Infants and Children

- Maternal HIV viral loads that categorize infants at a high risk of perinatal HIV transmission have been defined at HIV RNA ≥ 50 copies/mL.
- A statement has been added to clarify that HIV testing at birth might be considered when there are concerns that a newborn at low risk of perinatal HIV transmission may be lost to follow-up without testing.
- Content has been added about the potential for false-positive HIV nucleic acid tests (NATs) with chimeric antigen receptor T cell (CAR-T cell) and lentiviral-based gene therapy.

Initial Postnatal Management of the Neonate Exposed to HIV

- The Panel has added information about hyperbilirubinemia and has added a statement to point out that with appropriate follow-up to support the recommended diagnostic testing schedule, most infants with perinatal HIV exposure do not require trimethoprim-sulfamethoxazole prophylaxis, because HIV can be presumptively excluded by the time their infant ARV regimen is completed (see [Diagnosis of HIV Infection in Infants and Children](#)).

Appendix B: Supplement: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy.

- [Table 10: Antiretroviral Drug Use in Pregnant Women with HIV Infection: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy](#) and other sections in Appendix B have been updated with new data for each drug, including new formulations and fixed-dose combination tablets.
- [Tenofovir Alafenamide \(TAF\)](#) now includes data from the Antiretroviral Pregnancy Registry, which has monitored a sufficient number of first-trimester exposures to detect at least a twofold increase in the risk of overall birth defects; no such increase in risks has been observed with TAF.
- [Dolutegravir](#), [Elvitegravir](#), [Raltegravir](#) now include supplemental data about central nervous system birth defects from the Antiretroviral Pregnancy Registry.
- A new section was added for [Fostemsavir](#), a drug that has been approved by the Food and Drug Administration for use in adults.

December 15, 2020

Table 5. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant People and Nonpregnant People Who Are Trying to Conceive

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- Lopinavir/ritonavir is now classified as *Not Recommended Except in Special Circumstances*, rather than as an *Alternative* ARV, based on requirements for twice daily dosing, potential nausea and vomiting, and data about increased risks of preterm delivery and small for gestational age infants.

- The Panel now recommends tenofovir alafenamide (TAF) as an *Alternative* nucleoside reverse transcriptase inhibitor for ARV therapy regimens now that additional data about the use and safety of TAF in pregnancy has become available.
- The Panel has revised language about its recommendations for pregnant women who are currently receiving a cobicistat containing ARV regimens that pose a risk for low drug levels and viral rebound in the second and third trimesters to point out that some women may choose to continue with frequent viral load monitoring, rather than switching to a new regimen.
- Fostemsavir, a new ARV, has been classified as *Insufficient Data* for use in pregnancy.
- Upcoming publication of other sections will reflect these changes in the full Guidelines.