

What's New in the Guidelines

January 31, 2023

The Panel on Treatment of HIV in Pregnancy and Prevention of Perinatal Transmission (the Panel) has updated text and references throughout the guidelines to include new data and publications where relevant. These changes are highlighted in yellow in the PDF version of the guidelines. Some content has been reorganized among sections, with the creation of two new sections, changes to the sequence of some sections, and the addition of new tables to facilitate access to information. The Panel continues to move to the use of gender-neutral language but uses terms associated with female gender (e.g., mother, maternal) in some sections; this will continue to be reviewed in future updates.

Maternal HIV Testing and Identification of Perinatal HIV Exposure

- This section was revised for clarification and to provide explanatory content about HIV testing, including expedited HIV tests, during pregnancy and postpartum. Subsections were added on approved HIV tests and testing algorithms and false positive HIV tests.

Pre-Exposure Prophylaxis (PrEP) to Prevent HIV During Periconception, Antepartum, and Postpartum Periods

- This section was updated in accordance with the current Centers for Disease Control and Prevention guidelines for HIV PrEP. Long-acting cabotegravir (CAB) as PrEP may be initiated or continued in people who become pregnant.

Prepregnancy Counseling and Care for Persons of Childbearing Age With HIV

- This section was revised to clarify that—
 - The HIV status of one or both parents should not be a reason to withhold standard of care infertility treatment.
 - Providers should encourage individuals to disclose their HIV status to their partner or co-parent before pregnancy if it is safe to do so. However, this disclosure should not be a requirement for assisting couples in achieving pregnancy.

Antepartum Care for Individuals With HIV

- This section, formerly titled General Principles Regarding Use of Antiretroviral Drugs During Pregnancy, was revised to focus on pregnancy-related care, including support for antiretroviral therapy (ART) adherence during pregnancy.
- Content related to invasive procedures for prenatal screening, diagnosis, and therapy was moved into this section and a new table was added [Table 4. Antepartum Screenings and Assessments for Pregnant People With HIV](#).

Recommendations for the Use of Antiretroviral Drugs During Pregnancy: Overview

- The Panel has reorganized and revised content to provide a comprehensive overview on the individualized selection of antiretroviral (ARV) drugs and recommendations for the use of ARV drugs during pregnancy, with links to updated scenario-specific content in other sections and [Appendix C: Antiretroviral Counseling Guide for Health Care Providers](#). Drug-specific content, available in [Appendix B: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy](#), and drug-specific recommendations, available in scenario-specific sections and tables, were removed from this section.
- The selection of which ARVs to use during pregnancy is best made through shared decision-making between the health care provider and patient after discussing the known and potential risks and benefits to the patient and fetus, acknowledging limited data (AIII).
- The Panel points out that pregnancy, lactation, and the potential for pregnancy should not preclude the use of drug regimens that would be chosen for people who are not pregnant, unless adequate drug levels are not likely to be attained in pregnancy or there are known adverse effects that outweigh potential benefits (AIII).

Use of Antiretroviral Drugs to Prevent Perinatal HIV Transmission and Improve Maternal Health

- This is a new section that outlines core components and associated data about the use of ARV drugs before and during pregnancy to improve maternal health and prevent perinatal HIV transmission, including ARVs for newborns with perinatal HIV exposure. Some of the content and bulleted recommendations were moved and adapted from the section about Pregnant People Who Have Never Received Antiretroviral Drugs and other sections.

People With HIV Who Are Trying to Conceive

- This is a new section that was added to provide a short overview about recommendations regarding ART for people who are trying to conceive.
- The Panel recommends that the use of contraception, regardless of type, should not be required to initiate or continue ARVs that would otherwise be recommended for an individual patient, even if there are limited data in pregnancy (AIII). Clinicians should engage in shared decision-making, counsel on the potential benefits and risks, and be aware of the potential for reproductive coercion (AIII).
- Whenever possible, regimen initiation or changes should be made with sufficient time to achieve viral suppression before attempting to conceive or becoming pregnant (AII).

Pregnant People With HIV Who Have Never Received Antiretroviral Drugs

- This section was shortened by moving some content about the use of ARV drugs for perinatal HIV prevention to Use of Antiretroviral Drugs to Prevent Perinatal HIV Transmission and Improve Maternal Health and other sections; revisions were made to reflect updates to Panel recommendations described in [Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy For People Who Are Antiretroviral-Naive](#) and [Table 7. Situation-Specific](#)

Recommendations for Use of Antiretroviral Drugs in Pregnant People and Nonpregnant People Who Are Trying to Conceive.

People With HIV Who Are Taking Antiretroviral Therapy When They Become Pregnant

- The Panel recommends that pregnant people who present to care on long-acting injectable CAB and RPV during pregnancy should be counseled about limited data. The Panel now recommends that clinicians and pregnant people reach a shared decision about continuing this regimen with frequent viral load monitoring or switching to one of the *Preferred* or *Alternative* three-drug ARV regimens (CIII).
- Because pharmacokinetic (PK) changes during pregnancy—especially in the second and third trimester—may lead to a lower plasma level of some ARV drugs, the Panel recommends that clinicians consider the need for increased doses, more frequent dosing, boosting, more frequent viral load monitoring, or a change in the ARV regimen (AII).
- Revisions were made to address care for people who have achieved viral suppression and become pregnant while receiving regimens with a potential increased risk of virologic failure during pregnancy due to PK concerns (e.g., cobicistat-boosted regimens) or regimens with insufficient data about dosing and/or safety in pregnancy (e.g., bicitgravir [BIC], doravirine [DOR]).

Pregnant People Who Have Not Achieved Viral Suppression on Antiretroviral Therapy

- The bulleted recommendations were revised to align more closely with important content in the text.
- When lack of viral suppression is identified, the Panel recommends a thoughtful evaluation of potential contributing factors is needed. Such factors include barriers to adherence, drug resistance, PK changes in pregnancy leading to insufficient drug levels, and combinations of these factors. Management of lack of viral suppression should address each of these factors if relevant (AII).
- To detect problems with viral suppression early, more frequent viral load monitoring (every 1 to 2 months) is recommended when individuals are receiving regimens associated with lower drug levels in the third trimester or drugs with limited or no PK data on use in pregnancy (AII).

Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy for People Who Are Antiretroviral-Naive

- The table was revised to reflect updated Panel recommendations and to list the advantages and disadvantages of ARV combinations and regimens.

Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant People and Nonpregnant People Who Are Trying to Conceive

- The Panel now recommends raltegravir (RAL) and ritonavir-boosted atazanavir (ATV/r) as *Alternative* rather than *Preferred* ARVs for use in pregnancy and for people who are trying to conceive.
- Although there are insufficient data about the use of BIC and DOR in pregnancy, the Panel recommends that pregnant people who present on these regimens with a suppressed viral load may continue their current treatment with frequent viral load monitoring or consider switching to an ARV regimen that is recommended for use in pregnancy.
- Panel recommendations for long-acting injectable CAB and RPV were changed from *Not Recommended* to *Insufficient Data* for some situations in pregnancy. Counseling is recommended to support informed decisions about whether to continue with frequent viral load monitoring or consider switching to a three-drug regimen recommended for use in pregnancy.

Teratogenicity

- The Panel recommends that pregnant people with HIV should not delay initiating ART due to concerns about teratogenicity with first-trimester exposure (**AIII**).
- [Table 8. Drug-Specific Risk Assessment by the Antiretroviral Pregnancy Registry](#) was added to provide an overview of risk assessment across drugs.
- Some drug-specific teratogenicity content was deleted from this section because it is provided in [Appendix B. Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy](#).

Early (Acute and Recent) HIV Infection

- This section title was revised to align with the corresponding section in the [Adult and Adolescent Antiretroviral Guidelines](#).
- For pregnant people with early HIV infection who have previously used long-acting CAB as PrEP, the Panel recommends initiating ART with a ritonavir-boosted, darunavir-based regimen pending the results of genotype testing for integrase strand transfer inhibitor–resistance mutations (**AII**).

Infant Feeding for Individuals With HIV in the United States

- The former section, Counseling and Managing Individuals With HIV in the United States Who Desire to Breastfeed, was revised and retitled to provide more comprehensive guidance on feeding infants born to individuals with HIV. Content about breastfeeding in other sections was revised to align with and refer to updated recommendations in this section.
- The Panel recommends that people with HIV receive evidence-based, patient-centered counseling to support shared decision-making about infant feeding. Counseling about infant feeding should begin prior to conception or as early as possible in pregnancy; information about and plans for infant feeding should be reviewed throughout pregnancy and again after delivery (**AIII**). During counseling, people should be informed that—

- Replacement feeding with properly prepared formula or pasteurized donor human milk from a milk bank eliminates the risk of postnatal HIV transmission to the infant (AI).
- Achieving and maintaining viral suppression through ART during pregnancy and postpartum decreases breastfeeding transmission risk to less than 1%, but not zero (AI).
- Replacement feeding with formula or banked pasteurized donor human milk is recommended to eliminate the risk of HIV transmission through breastfeeding when people with HIV are not on ART and/or do not have a suppressed viral load during pregnancy (at a minimum throughout the third trimester), as well as at delivery (AI).
- Individuals with HIV who are on ART with a sustained undetectable viral load and who choose to breastfeed should be supported in this decision (AIII).
- Individuals with HIV who choose to formula feed should be supported in this decision; potential barriers to formula feeding should be identified and addressed (AIII).
- Content about counseling and management of individuals who choose to breastfeed was updated, with added content on situations in which to consider stopping or modifying breastfeeding.

Antiretroviral Management of Newborns With Perinatal HIV Exposure or HIV Infection

- When the criteria for low risk of perinatal HIV transmission are met, the Panel now recommends that infants receive 2 weeks of zidovudine (ZDV) prophylaxis, rather than 4 weeks (see [Table 10. Neonatal Antiretroviral Management According to Risk of HIV Infection in the Newborn](#)).
- Infants born to individuals who do not meet the criteria for low risk of perinatal HIV transmission but who have a viral load <50 copies/mL at or after 36 weeks should receive ZDV for 4 to 6 weeks (BII).
 - The criterion for viral suppression was further defined as at least two consecutive tests with HIV RNA levels <50 copies/mL obtained at least 4 weeks apart.
- The Panel clarified the duration of ARVs for newborns at high risk of perinatal acquisition. Presumptive HIV therapy with three-drug regimens should be administered from birth for 2 to 6 weeks (see [Tables 10](#) and [11](#)); if the duration of the three-drug regimen is shorter than 6 weeks, ZDV should be continued alone, to complete total of 6 weeks of prophylaxis.
- All premature infants <37 weeks gestation who are not at high risk of perinatal acquisition of HIV should receive ZDV for 4 to 6 weeks (BII).
- New subsections and [Table 12. Infant Antiretroviral Prophylaxis for Newborns of Mothers with Sustained Viral Suppression Who Breastfeed](#) were added to address ARV prophylaxis for newborns at low risk of perinatal HIV transmission who are breastfed and to provide information about breastfeeding in newborns at high risk of perinatal HIV acquisition.

Diagnosis of HIV Infection in Infants and Children

- This section now provides additional guidance on HIV diagnostic testing for infants with perinatal HIV exposure who are being breastfed in the text and in [Table 13. Recommended Virologic Testing Schedules for Infants Who Were Exposed to HIV According to Risk of Perinatal HIV Acquisition at and After Birth](#).

- A subsection was added with information about HIV testing for infants who were being breastfed at the time of maternal HIV diagnosis.

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

- [Table 14. Antiretroviral Drug Use in Pregnant People With HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy](#) was updated, and dosing recommendations for pregnant people are now listed first for each drug.
- In [Appendix B: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy](#), summary bullet points about PKs and dosing, teratogenicity, and safety or other issues were added to each of the individual drug sections. Sections were updated with new data, where indicated, and content was reorganized to provide information about human studies prior to that about animal studies.