What's New in the Guidelines

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.

December 30, 2021

Introduction

As part of continuing efforts to be inclusive of transgender and gender diverse individuals assigned female sex at birth, the Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission (the Panel) has made revisions to incorporate gender inclusive language; for example, using “pregnant people” or “pregnant patients” versus “pregnant women” where appropriate. When reviewing data, results will be presented using the same terms used in the studies and publications being described, such as “pregnant women.” A new section has been added to address the unique needs of this population, Perinatal HIV Prevention for Transgender and Gender Diverse People Assigned Female Sex at Birth, in addition to content available in the Adult and Adolescent Antiretroviral Guidelines (see Transgender People with HIV).

Maternal HIV Testing and Identification of Perinatal HIV Exposure

Section content has been updated to include a list of states with statutes or regulations that require repeat HIV testing in the third trimester and to recommend that this testing be offered to pregnant people who perceive themselves at increased risk for HIV infection.

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

- Because HIV risk factors may be underreported, the Panel recommends that health care providers discuss PrEP with those with behaviors or experiences that can be associated with HIV, such as intimate partner violence and repeated post-exposure prophylaxis courses.
- The section has been reorganized to focus initially on clinical management of PrEP use with updated and additional content.

Prepregnancy Counseling and Care for Persons of Childbearing Age with HIV

- This section has been retitled in alignment with the transition from preconception care to prepregnancy care by the American College of Obstetricians and Gynecologists.
- Prepregnancy counseling and care has been updated to include vaccination to SARS-CoV-2 and considerations for the care of gender diverse and transgender individuals.

Reproductive Options for Couples When One or Both Partners Have HIV

- The section has been updated to address family building options for people with HIV across the spectrum of gender identity and sexual orientation.
**General Principles Regarding Use of Antiretroviral Drugs During Pregnancy**

- Recommendations and content about stopping antiretroviral (ARV) drugs during pregnancy have been incorporated into this section rather than presented in a separate section.

**Teratogenicity**

- Based on a study conducted in cynomolgus monkeys, suggesting that ibalizumab (IBA) may cause reversible immunosuppression in infants born to mothers exposed to IBA during pregnancy, expert consultation is recommended for guidance on monitoring and management of infants exposed to this drug based on the degree of immunosuppression observed.

**Recommendations for Use of Antiretroviral Drugs During Pregnancy**

- The Panel continues to recommend dolutegravir (DTG) as a *Preferred* ARV drug for pregnant people, irrespective of trimester, and for people who are trying to conceive. The most recent data from the Tsepamo study in Botswana indicate that, although the prevalence of infant neural tube defects (NTDs) with periconception use of DTG was higher than the prevalence of NTDs in infants born to women who were receiving efavirenz and women without HIV, the prevalence was not significantly increased compared with women with HIV receiving non-DTG ARV regimens at conception. Based on these and other data, the Panel has removed bulleted recommendations with DTG-specific cautions.

- Based on additional data about the use and safety of tenofovir alafenamide (TAF), the Panel now recommends TAF as a *Preferred* nucleoside reverse transcriptase inhibitor for ARV regimens in people who are pregnant or are trying to conceive.

- Available data about weight gain with TAF and with DTG during pregnancy have been reviewed and incorporated in this section.

- Oral cabotegravir (CAB) and the new long-acting injectable regimen of CAB and rilpivirine (RPV) have been classified as *Not Recommended* for use in pregnancy and as *Insufficient Data* for persons who are trying to conceive or who become pregnant while on this regimen.

- Revisions have been made to the sections listed below to incorporate the Panel’s updated recommendations about ARV drugs during pregnancy and for people who are trying to conceive.
  - Pregnant People with HIV Who Have Never Received Antiretroviral Drugs (Antiretroviral Naive)
  - Table 4. What to Start: Initial Antiretroviral Regimens During Pregnancy for People Who Are Antiretroviral-Naive
  - Table 5. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant People and Nonpregnant People Who Are Trying to Conceive
  - Pregnant People with HIV Who Are Currently Receiving Antiretroviral Therapy
  - Appendix C: Antiretroviral Counseling Guide for Health Care Providers

**Pregnant People with HIV Who Are Currently Receiving Antiretroviral Therapy**

- Although no data exist on the use of two-drug oral ARV regimens during pregnancy (e.g., DTG plus lamivudine [3TC], DTG plus RPV), the component drugs are recommended for use in
pregnancy. The Panel recommends that pregnant persons who present to care on DTG/3TC or DTG/RPV and have successfully maintained viral suppression can continue the two-drug regimen with more frequent viral load monitoring, every 1 to 2 months throughout pregnancy (CII).

- For people with HIV who have achieved virologic suppression and become pregnant while receiving ARV drugs with insufficient data about their use in pregnancy—such as bictegravir (BIC) or doravirine—clinicians should consider whether to continue or change the regimen, because a regimen change carries a risk for viral rebound at the time of the switch. If a decision is made with the patient to continue the same regimen, viral load should be monitored more frequently (i.e., every 1 to 2 months).

- Because data about the use of long-acting injectable CAB and RPV during pregnancy are extremely limited, the Panel recommends that pregnant persons who present to care on this regimen should be switched to a Preferred or Alternative three-drug ARV regimen recommended for use in pregnancy (CIII).

**Monitoring During Pregnancy**

- The section was updated to address the risk for weight gain and obesity that may be present with integrase inhibitor use during pregnancy and postpartum.

**Hepatitis B Virus/HIV Coinfection**

- The Panel added a recommendation to clarify that hepatitis B virus/HIV coinfection is not an independent indication for cesarean delivery (AIII).

**Hepatitis C Virus/HIV Coinfection**

- The Panel added a recommendation to clarify that hepatitis C virus/HIV coinfection is not an independent indication for cesarean delivery (AIII).

**HIV-2 Infection and Pregnancy**

- Now that TAF is a Preferred ARV drug for use in pregnancy, it has been added to recommended options in ARV regimens for the treatment of HIV-2 infection during pregnancy.

**Acute HIV**

- The Panel recommends DTG plus tenofovir disoproxil fumarate (TDF) or TAF with emtricitabine (FTC) or 3TC as the Preferred ARV regimen for pregnant people with acute HIV, irrespective of trimester (AII). Ritonavir-boosted darunavir (DRV/r) plus TDF or TAF with FTC or 3TC is an Alternative ARV regimen for pregnant people with acute HIV (AIII). See Table 4, Table 5, and Recommendations for Use of Antiretroviral Drugs During Pregnancy for more information.

- One of the following ARV regimens is recommended for people diagnosed with acute HIV infection when they are breastfeeding: BIC/TAF/FTC; DTG with TAF or TDF plus FTC or 3TC; boosted DRV with TAF or TDF plus FTC or 3TC (AIII) (see Acute and Recent [Early] HIV Infection in Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV).
Perinatal HIV Prevention for Transgender and Gender Diverse People Assigned Female Sex at Birth

- This section provides an overview about the Panel’s recommendations regarding perinatal HIV prevention and treatment of HIV in pregnancy for transgender and gender diverse people assigned female sex at birth.

- The Panel has determined that, in most cases, it is appropriate to extrapolate its recommendations based on data in presumed cisgender women to all people assigned female sex at birth, including transgender and gender diverse people, with modification when indicated (e.g., drug interactions with gender-affirming hormones) (AIII).

- Patient-centered HIV and perinatal services should be provided using gender-affirming and shared decision-making approaches and models of care that address the unique and varied needs of transgender and gender diverse people and reduce barriers to ongoing engagement in care that can affect adherence to ARV therapy and the likelihood of viral suppression during prepregnancy, antepartum, and postpartum periods (AII).

- Health care providers should assess reproductive and parenting intentions and support access to appropriate contraception and perinatal HIV prevention services for transgender and gender diverse people (AIII).

- Some transgender and gender diverse patients may experience the onset or worsening of gender dysphoria and associated symptoms—such as depression—during prepregnancy, antepartum, and postpartum periods; health care providers should regularly assess patients’ comfort with their care and provide referrals for mental health or other support services as needed (AIII).

Intrapartum Care for People with HIV

- The Panel has clarified when viral load tests should be done to inform decisions about mode of delivery and need for intravenous zidovudine prophylaxis during labor, changing from “near delivery” to “within 4 weeks of delivery/anticipated delivery.”

Counseling and Managing Individuals with HIV in the United States Who Desire to Breastfeed

- Guidance about ARV prophylaxis for breastfeeding infants has been updated to address the provision of infant prophylaxis beyond the recommended time period of 4 weeks in an infant of a parent receiving ART with viral suppression, which is controversial; see Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection.

Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection

- The Panel has clarified when viral load tests should be done to inform decisions about ARV prophylaxis or presumptive HIV therapy for infants with perinatal HIV exposure, changing from “near delivery” to “within 4 weeks prior to delivery.”

- Table 9. Antiretroviral Drug Dosing Recommendations for Newborns has been updated to include abacavir (ABC) dosing recommendations for infants and nevirapine dosing for infants ≥32 to <34 weeks’ gestation at birth. The Panel does not recommend ABC for presumptive HIV therapy. However, in situations where ZDV is not available or the infant has ZDV-associated
toxicity, ABC could be considered an alternative to ZDV. Because of ABC-associated hypersensitivity, negative testing for HLA-B5701 allele should be confirmed prior to administration of ABC.

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

- Table 11: Antiretroviral Drug Use in Pregnant People with HIV Infection: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy and the individual drug sections in Appendix B have been updated with new data for each drug, and a new section has been added for Cabotegravir.