What's New in the Guidelines

January 31, 2024

The Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission (the Panel) has updated text and references throughout the guidelines to include new data and publications where relevant and to incorporate gender-inclusive language. These changes are highlighted in yellow in the PDF version of the guidelines. The shared sections with the Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV—Diagnosis of HIV Infection in Infants and Children, Infant Feeding for Individuals with HIV in the United States, and Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection—are still being revised; it is anticipated that these sections will be published in April 2024.

- Throughout the guidelines, minor changes were made to the HIV RNA threshold for resistance testing to be consistent with the Drug-Resistance Testing section in the Adult and Adolescent Antiretroviral Guidelines.
- Review of Clinical Trials of Antiretroviral Interventions to Prevent Perinatal HIV Transmission, the former Appendix A that provided information about the historical context of perinatal HIV prevention, has been archived; see Perinatal Archived Guidelines.

Introduction

- This section has been revised to clarify terms and present recent data about perinatal HIV transmission (i.e., during pregnancy and labor and delivery) and postnatal HIV transmission (i.e., through breastfeeding).

Pregnancy and Postpartum HIV Testing and Identification of Perinatal and Postnatal HIV Exposure

- Revisions have been made to the section title and bulleted recommendations and throughout the text to provide added detail, new data, and clarification.
- The Panel recommends that when acute HIV infection is suspected during pregnancy, the intrapartum period, or while breastfeeding, a plasma HIV RNA assay should be performed in conjunction with an antigen/antibody immunoassay.

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

- Given the lack of data, episodic or non-daily PrEP is not recommended for protection against vaginal exposure to HIV.
- For people planning to discontinue daily oral PrEP, ongoing use for 7 to 28 days after last HIV exposure is recommended. This timeframe aligns with recommendations for post-exposure prophylaxis.

- For people who become pregnant while receiving PrEP, including drugs not yet approved for PrEP during pregnancy (e.g., long-acting injectable cabotegravir [CAB-LA], tenofovir alafenamide [TAF]), clinicians are strongly encouraged to register them with the Antiretroviral Pregnancy Registry as early in pregnancy as possible.
- Efficacy studies evaluating TAF/emtricitabine (FTC) as PrEP in people with vaginal exposure have not been completed. Therefore, the Panel does not recommend TAF/FTC as PrEP for this population, including during pregnancy and postpartum. Additionally, TDF/FTC pharmacokinetic data cannot be readily extrapolated to TAF/FTC.

Reproductive Options When One or Both Partners Have HIV

- Rescreening for genital tract infections while attempting to conceive may be considered based on individual risk and duration of the preconception period.
- To prevent HIV acquisition, the Panel recommends that health care providers discuss PrEP with all sexually active people without HIV, including individuals who are trying to conceive. PrEP should be offered to those who desire PrEP or have specific indications for PrEP.

Initial Evaluation and Continued Monitoring of HIV During Pregnancy

- Revisions have been made to clarify recommendations for CD4 T lymphocyte cell count monitoring that align with guidance in the Adult and Adolescent Antiretroviral Guidelines.

Antiretroviral Therapy for People with HIV Who Are Trying to Conceive

- Data are not available about the efficacy and safety of injectable cabotegravir (CAB) and rilpivirine (RPV) during pregnancy. For those who are considering switching regimens prior to conception to prevent fetal exposure, it is important to recognize that CAB and RPV injections must be stopped at least 1 year before conception to ensure that these long-acting drugs are fully eliminated.
- Among those on long-acting injectable antiretroviral therapy (ART) who have a history of poor adherence to oral medications, switching from long-acting injectable CAB and RPV to oral ART to prepare for conception may be associated with increased risk of viral rebound and non-nucleoside reverse transcriptase inhibitor resistance. Shared decision-making should be used when making decisions about changing to an oral regimen.

Pregnant People with HIV Who Have Never Received Antiretroviral Drugs (Antiretroviral-Naive)

- The following dolutegravir (DTG)-based regimens are *Preferred* as initial ART for pregnant people who have never received antiretroviral (ARV) drugs:
  - DTG plus (tenofovir disoproxil fumarate [TDF] or TAF) plus (FTC or lamivudine [3TC]) *or*
  - DTG plus abacavir (ABC) plus 3TC—only for individuals who are HLA-B*5701 negative and without chronic hepatitis B virus (HBV) coinfection

- However, in people with a history of CAB exposure for PrEP, the following ritonavir-boosted darunavir (DRV/r)–based regimens are *Preferred* for initial ART due to concerns about integrase strand transfer inhibitor (INSTI) resistance mutations:
  - DRV/r plus (TDF or TAF) plus (FTC or 3TC) *or*
  - DRV/r plus ABC plus 3TC—only for individuals who are HLA-B*5701 negative and without HBV coinfection
- In other situations, DRV/r is now recommended as an *Alternative* rather than a *Preferred* ARV for use in pregnancy; see Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant People and Nonpregnant People Who Are Trying to Conceive.
- Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy for People Who Are Antiretroviral-Naive has been revised to reflect updated Panel recommendations for persons who are ARV naive and list the advantages and disadvantages of ARV combinations and regimens.

Pregnant People Who Have Not Achieved Viral Suppression on Antiretroviral Therapy

- Revisions were made to update bulleted recommendations and text on the definition, evaluation, and management of lack of viral suppression and virologic failure.
- The Panel does not recommend adding a single ARV drug to a virologically failing regimen. The Adult and Adolescent Antiretroviral Guidelines discuss specific regimen modifications for situations in which viral suppression has not been achieved or where there has been a rebound of viral load (see Virologic Failure) that can be considered in conjunction with Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant People and Nonpregnant People Who Are Trying to Conceive.

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

- Based on new data about pharmacokinetics in pregnancy and updated information in the Antiretroviral Pregnancy Registry, bictegravir (BIC) is now recommended as an *Alternative* ARV for use in pregnancy and for people who are trying to conceive; it was previously categorized as *Insufficient Data to Recommend* use in pregnancy. Data are still limited, but no safety concerns have been observed.
- DRV/r is now recommended as an *Alternative* rather than a *Preferred* ARV for use in pregnancy and for people who are trying to conceive. However, in pregnant people with a history of CAB exposure for PrEP, DRV/r is a *Preferred* ARV for initial ART regimens due to concerns about INSTI resistance mutations.
- DRV/r, rather than ritonavir-boosted atazanavir (ATV/r), is recommended as an option for initial ART in nonpregnant adults. However, DRV/r requires twice-daily dosing in pregnancy, and dosing frequency affects ARV adherence. For this reason, when a protease inhibitor–based regimen is indicated in pregnancy, some Panel members would use ATV/r rather than DRV/r.
- Panel recommendations for fostemsavir and ibalizumab (IBA) have been revised from *Not Recommended* to *Not Recommended Except in Special Circumstances* since they may be needed for some pregnant people with extensive treatment experience.

- Appendix C. Antiretroviral Counseling Guide for Health Care Providers has been updated to incorporate changes in the tables and text sections that address recommendations regarding the use of specific ARV drugs in pregnancy.

HIV-2 Infection and Pregnancy

- BIC was added to the ARV drugs that are recommended for treating HIV-2 infection during pregnancy and for people who are trying to conceive.
    - For patients with multidrug-resistant virus, IBA and lenacapavir (LEN) demonstrate *in vitro* potency against HIV-2 and may be considered; these drugs are *Not Recommended Except in Special Circumstances* for use in pregnancy.

Early (Acute and Recent) HIV Infection

- Based on changes to Panel recommendations on the use of BIC in pregnancy, BIC plus TAF plus FTC is now recommended as an *Alternative* ART regimen for pregnant people with early infection and without a history of prior use of CAB-LA as PrEP.

Initial Postnatal Management of the Neonate Exposed to HIV

- Information about recommended testing for viral coinfections in the infants with perinatal HIV exposure (e.g., congenital cytomegalovirus, hepatitis C virus, HBV) with links to resources about testing and care has been added.

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 and the individual drug sections have been reviewed and updated. A new drug section was added for LEN. Although limited data in animals have not identified reproductive safety concerns, no data in humans are available about the use of LEN in pregnancy.