Early (Acute and Recent) HIV Infection

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Panel's Recommendations

- When early[a] (acute and recent) HIV infection is suspected during pregnancy, the postpartum period, or breastfeeding, a plasma HIV RNA test should be obtained in conjunction with an antigen/antibody immunoassay test (AII). See Early (Acute and Recent) HIV Infection in the Adult and Adolescent Antiretroviral Guidelines and the Centers for Disease Control and Prevention HIV testing algorithm for more information.
- Repeat HIV testing in the third trimester is recommended for pregnant people with initial negative HIV test results who are at increased risk of acquiring HIV, including those receiving care in facilities that have an HIV incidence of ≥1 case per 1,000 pregnant women per year, those who reside in jurisdictions with elevated HIV incidence (see Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings), or those who reside in states that require third-trimester testing (see Maternal HIV Testing and Identification of Perinatal HIV Exposure) (AII).
- All pregnant and breastfeeding people with early HIV infection should start antiretroviral therapy (ART) as soon as possible for their own health and to reduce the risk of perinatal or horizontal HIV transmission, with the goal of rapidly suppressing plasma HIV RNA below detectable levels (AI).
- In people with early HIV infection, baseline genotypic resistance testing should be performed simultaneously with initiation of ART, and the regimen should be adjusted, if necessary, to optimize virologic response (AII).
- The following regimens are recommended for pregnant people with early infection without a history of prior use of long-acting cabotegravir (CAB-LA) as pre-exposure prophylaxis (PrEP):
  - Dolutegravir (DTG) plus tenofovir disoproxil fumarate (TDF) or tenofovir alafenamide (TAF) with emtricitabine (FTC) or lamivudine (3TC) is the *Preferred* ART irrespective of trimester (AII).
  - Ritonavir-boosted darunavir (DRV/r) plus (TDF or TAF) with (FTC or 3TC) is an *Alternative* ART regimen (AIII).
  - See Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy for People Who Are Antiretroviral-Naive, Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant People and Nonpregnant People Who Are Trying to Conceive, Recommendations for Use of Antiretroviral Drugs During Pregnancy, Appendix C: Antiretroviral Counseling Guide for Health Care Providers, and Early (Acute and Recent) HIV Infection in the Adult and Adolescent Antiretroviral Guidelines for more information.
- For pregnant people with early infection with a history of prior use of CAB-LA as PrEP, genotype testing done before the start of ART should include screening for integrase strand transfer inhibitor–resistance mutations:
  - A regimen of DRV/r with (TDF or TAF) plus (FTC or 3TC) is the *Preferred* ART regimen pending results of genotype testing (AIII). See Early (Acute and Recent) HIV Infection in the Adult and Adolescent Antiretroviral Guidelines for more information.
- One of the following regimens is recommended for people diagnosed with early HIV infection during the postpartum period: bictegravir/TAF/FTC; DTG with (TAF or TDF) plus (FTC or 3TC); or DRV/r with (TAF or TDF) plus (FTC or 3TC) (AIII). See Early (Acute and Recent) HIV Infection in the Adult and Adolescent Antiretroviral Guidelines for more information.
- People who receive a diagnosis of HIV infection when they are breastfeeding should be counseled to discontinue breastfeeding immediately to reduce the risk of postnatal HIV transmission to the infant (AII).
- The Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission emphasizes the importance of counseling and informed decision-making regarding all antiretroviral (ARV) regimens for people with HIV (AIII).
- Providers should inform individuals starting ART of the importance of strict adherence to rapidly achieve and maintain viral suppression (AIII).

• Infants born to people who received a diagnosis of early HIV infection during pregnancy or breastfeeding are at high risk of acquiring HIV infection and should receive an ARV regimen that is appropriate for this elevated risk (see Table 10. Neonatal Antiretroviral Management According to Risk of HIV Infection in the Newborn in Antiretroviral Management of Newborns With Perinatal HIV Exposure or HIV Infection) (AII). Consulting a pediatric HIV specialist regarding appropriate infant management is strongly recommended.
Rating of Recommendations: A = Strong; B = Moderate; C = Optional *Rating of Evidence: 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*

[a] Early HIV infection represents either acute or recent HIV infection.

Women may have an increased risk of HIV infection during pregnancy or breastfeeding.[1-3] Persons who are at risk for acquiring HIV during pregnancy and the postpartum period should consider using interventions that prevent HIV acquisition, such as oral daily pre-exposure prophylaxis (PrEP).[4] For more information, see Pre-Exposure Prophylaxis (PrEP) to Prevent HIV During Periconception, Antepartum, and Postpartum Periods.

Risk of Perinatal Transmission After Maternal Early HIV Infection

Early HIV infection is a term that encompasses acute or recent infection. During pregnancy or breastfeeding, early infection is associated with an increased risk of perinatal HIV transmission, and a significant proportion of pediatric infections can be attributed to maternal acute infection.[5] Among 10,308 pregnant women with HIV who delivered live infants from 2005 to 2010 in 15 areas of the United States that conducted enhanced perinatal surveillance, 124 women (1.2%) seroconverted during pregnancy. The rate of perinatal transmission was eight times higher among women who seroconverted during pregnancy (12.9%) than among those who seroconverted before pregnancy (1.6%) ($P < 0.0001$).[6] Similarly, among 108 new perinatal HIV infections that were identified between 2006 and 2013 in the United Kingdom, 23 (21.3%) were associated with a concurrent maternal seroconversion.[7] The high rate of transmission in people with acute infection likely is related to the high viral loads in plasma, breast milk, and the genital tract that are present during acute infection.[8] Acute HIV infection can be asymptomatic or symptoms can be nonspecific, which results in missed opportunities to diagnose and implement interventions that can reduce the risk of perinatal transmission.

Diagnosis of Early (Acute or Recent) HIV Infection During Pregnancy, Postpartum, or Breastfeeding

Acute HIV infection occurs immediately after acquisition and is typically characterized by high viremia detected by the presence of HIV RNA or p24 antigen. Anti-HIV antibodies are not detectable early during this phase of HIV infection (see Early (Acute and Recent) HIV Infection section of the Adult and Adolescent Antiretroviral Guideline). Recent HIV infection generally is considered the phase of HIV disease ≤6 months after infection, during which anti-HIV antibodies develop and become detectable.[9-14] Health care providers should maintain a high level of suspicion of HIV infection in patients who are pregnant or breastfeeding and have clinical signs and symptoms that are compatible with acute infection. Even when patients do not report high-risk behaviors, it is still possible that their sexual partners are practicing high-risk behaviors without their knowledge or that they do not recognize that such behaviors put them at risk for HIV acquisition. An estimated 40% to 90% of patients with acute HIV infection will experience symptoms of acute retroviral syndrome,

which is characterized by fever, lymphadenopathy, pharyngitis, skin rash, myalgias/arthralgias, headache, diarrhea, oral ulcers, and other symptoms.[15-19] Providers often do not recognize acute HIV infection because the symptoms are similar to those of other common illnesses, and some individuals with acute HIV infection may be asymptomatic.

When early HIV infection is suspected during pregnancy or breastfeeding, a quantitative or qualitative plasma HIV RNA test should be obtained in conjunction with an antigen/antibody immunoassay test. Guidance for HIV testing recommends using a U.S. Food and Drug Administration–approved antigen/antibody combination (fourth-generation) immunoassay that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen for initial testing. These tests are used to screen for established infection with HIV-1 or HIV-2 and for early HIV-1 infection. More specific guidance on HIV testing can be found in the Early (Acute and Recent) HIV Infection section of the Adult and Adolescent Antiretroviral Guidelines, the Centers for Disease Control and Prevention (CDC) HIV testing algorithm, and the Maternal HIV Testing and Identification of Perinatal HIV Exposure section. People who acquire HIV while taking PrEP may sometimes have ambiguous HIV test results that may require additional testing. See Early (Acute and Recent) HIV Infection in the Adult and Adolescent Antiretroviral Guidelines and Pre-exposure Prophylaxis (PrEP) to Prevent HIV During Periconception, Antepartum, and Postpartum Periods for more information on diagnosing acute HIV infection in people taking PrEP.

Early HIV infection also can be detected by repeat HIV testing later in pregnancy in people whose initial HIV test was negative.[20] A report from the Mother-Infant Rapid Intervention at Delivery (MIRIAD) study found that 6 of 54 women (11%) whose HIV was identified with rapid HIV testing during labor had acute or recent infection.[21] Repeat testing during the third trimester is recommended for pregnant women who are known to be at risk of HIV infection, who receive care in facilities with an HIV incidence of ≥1 case per 1,000 pregnant women per year, or who reside in jurisdictions with elevated HIV incidence or with statutes and regulations that require third trimester testing[22,23] (see Prenatal and Perinatal Human Immunodeficiency Virus Testing; Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings; the CDC HIV testing algorithm; and Maternal HIV Testing and Identification of Perinatal HIV Exposure). Implementation of the recommendation for repeat HIV testing later in pregnancy has varied. A retrospective cohort study at a large metropolitan hospital in a high-prevalence jurisdiction in Maryland reported that repeat prenatal HIV testing was performed in only 28.4% of women.[24] In states with mandated late trimester HIV testing, reported rates of retesting are substantially higher. At a large, urban tertiary hospital in Florida, 82% of women were retested in the third trimester.[25] Similarly, a single high-volume birthing center in Illinois reported an increase in repeat testing from 80% to 98% after implementing measures to comply with the state's third-trimester testing mandate.[26]

Antiretroviral Therapy for People With Acute or Recent HIV Infection During Pregnancy or the Postpartum Period

Acute or recent HIV infection during pregnancy, postpartum, or breastfeeding is associated with a high risk of vertical transmission of HIV.[1,5] Therefore, all pregnant people with acute or recent HIV infection should start antiretroviral therapy (ART) as soon as possible to rapidly achieve and sustain plasma viral suppression, for their own health and to prevent perinatal and horizontal transmission. Baseline genotypic resistance testing should be performed to guide adjustment of an optimal antiretroviral (ARV) drug regimen. Data from the United States and Europe demonstrate that in 6% to 19% of patients, transmitted virus may be resistant to ≥1 ARV drugs.[27-29] If results of resistance

testing are already available or the source virus's resistance pattern is known, that information can be used to guide the selection of the drug regimen. The Panel on Antiretroviral Guidelines for Adults and Adolescents does not currently recommend routine genotype testing for integrase strand transfer inhibitor (INSTI) resistance in treatment-naive individuals, with the exception of individuals who acquire infection during or after the use of long-acting cabotegravir (CAB-LA) as PrEP (see Early (Acute and Recent) HIV Infection in the Adult and Adolescent Antiretroviral Guidelines for more information).

In pregnant people who have not received CAB-LA prior to diagnosis of acute/recent HIV infection, a regimen that includes dolutegravir (DTG) plus tenofovir disoproxil fumarate (TDF) or tenofovir alafenamide (TAF) plus emtricitabine (FTC) or lamivudine (3TC) should be initiated (see Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy for People Who Are Antiretroviral-Naive, Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant People and Nonpregnant People Who Are Trying to Conceive, Appendix C: Antiretroviral Counseling Guide for Health Care Providers, and Early (Acute and Recent) HIV Infection in the Adult and Adolescent Antiretroviral Guidelines for more information). DTG is associated with higher rates of viral suppression, faster rates of viral load decline, and a higher genetic barrier to drug resistance than other *Preferred* and *Alternative* agents. DTG plus TDF (or TAF) plus FTC (or 3TC) is one of the recommended ARV regimens for treatment of acute and early infection in nonpregnant adults. For pregnant people with early infection and a history of prior use of CAB-LA as PrEP, genotype testing done before the start of ART should include screening for INSTI-resistance mutations, and a regimen of ritonavir-boosted darunavir (DRV/r) (administered twice daily during pregnancy) plus (TDF or TAF) plus (FTC or 3TC) (see 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) should be initiated. The regimen can be adjusted once drug resistance results are available. In the case that the pregnant person cannot receive DTG (e.g., intolerance, potential transmitted resistance), DRV/r plus (TDF or TAF) plus (FTC or 3TC) should be administered. TDF (or TAF) plus (FTC or 3TC) are *Preferred* nucleoside reverse transcriptase inhibitor (NRTI) backbones for treatment of early infection. The efficacy and toxicity of TDF and TAF in pregnant patients are similar. In the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) 2010 trial, no differences were observed in viral suppression, Grade 3 or higher adverse events, or estimated creatinine clearance among people randomized to initiate TDF/FTC (n = 215) versus TAF/FTC (n = 217) with DTG at >14 weeks gestational age.[30] Abacavir (ABC) **is not recommended** for empiric treatment of acute infection unless the patient previously tested negative for the HLA-B*5701 gene variant; using TDF or TAF rather than ABC will avoid delays in ART initiation while awaiting HLA-B*5701 test results.

Several studies have demonstrated that the use of DTG-based regimens is associated with shorter time to viral suppression compared with other ARV regimens.[30-35] Although no data are available to inform the treatment of early HIV during pregnancy, two studies in pregnant women demonstrated more rapid viral decline on DTG-based regimens than on efavirenz (EFV)-based ART. In the DolPHIN 2 study (dolutegravir in pregnant HIV mothers and their neonates), 268 ART-naive pregnant women in Uganda and South Africa with a median gestational age of 31 weeks were randomized to receive either DTG plus two NRTIs or EFV plus two NRTIs. At delivery, women in the DTG arm were significantly more likely to have achieved HIV RNA <50 copies/mL than those in the EFV arm (74% vs. 43%, respectively; adjusted risk ratio 1.66 [95% confidence interval, 1.3–2.1]; $P < 0.0001$).[34] In the IMPAACT 2010 trial, 643 pregnant women, 14–28 weeks gestation, were assigned randomly to receive DTG plus FTC and TDF, DTG plus FTC and TAF, or EFV plus FTC

and TDF. At delivery, 395 (98%) of 405 participants in the combined DTG-containing groups had viral suppression, HIV-1 RNA <200 copies per mL, compared with 182 (91%) of 200 participants in the EFV plus FTC and TDF group. Furthermore, participants assigned to a DTG-containing group had a significantly shorter time to viral suppression than those in the EFV-containing group.[30]

People who are diagnosed with acute or recent HIV postpartum should start ART as soon as possible. ART options and management should follow guidance outlined in Early (Acute and Recent) HIV in the Adult and Adolescent Antiretroviral Guidelines. One of the following ART regimens is recommended: bictegravir/TAF/FTC; DTG with (TAF or TDF) plus (FTC or 3TC); or boosted DRV with (TAF or TDF) plus (FTC or 3TC).

Obstetrical and Neonatal Considerations

When early HIV infection is diagnosed during pregnancy, and particularly when it is documented in late pregnancy, cesarean delivery may be necessary when there is insufficient time to fully suppress a patient's viral load (see Intrapartum Care for People With HIV). In situations where individuals have not received at least 10 weeks of ART with viral load suppressed to <50 copies/mL for 4 weeks prior to delivery or in the setting of acute HIV infection, the infant should receive an ARV regimen that is appropriate for infants at elevated risk for HIV acquisition (see Antiretroviral Management of Newborns With Perinatal HIV Exposure or HIV Infection). The infant also should receive immediate diagnostic testing (see Diagnosis of HIV Infection in Infants and Children). Consulting a pediatric HIV specialist regarding appropriate infant management is strongly recommended.

When HIV infection is diagnosed during breastfeeding, breastfeeding should be discontinued immediately. In nursing mothers with suspected seroconversion, breastfeeding should be interrupted immediately, and it should not resume if infection is confirmed (see Situations to Consider Stopping or Modifying Breastfeeding in Infant Feeding for Individuals With HIV in the United States). Patients can continue to express and store breast milk while awaiting confirmation of infection status. Due to the high risk of postnatal transmission associated with early infection in pregnancy and during breastfeeding, this guidance is more directive than the shared decision-making recommended for individuals on suppressive ART.

All people who receive a diagnosis of infection should be asked whether they know the HIV status of their partners. HIV testing of the sexual partners of all pregnant people who test HIV positive should be encouraged, and PrEP should be offered to partners who test HIV negative.

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