Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States
### Panel's Recommendations

- HIV testing is recommended as a standard of care for all sexually active women and should be a routine component of preconception care (AII).
- All women should be tested as early as possible during each pregnancy (see Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations and Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens from the Centers for Disease Control and Prevention [CDC]) (AII).
- Partners of all pregnant women should be referred for HIV testing when their status is unknown (AIII).
- Repeat HIV testing in the third trimester is recommended for pregnant women with negative initial HIV antibody tests 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 from CDC), or those who reside in states that require third-trimester testing (AII).
- Repeat HIV testing is recommended for pregnant women with a sexually transmitted infection (STI) or with signs and symptoms of acute HIV infection (AIII).
- Expedited HIV testing should be performed during labor or delivery for women with undocumented HIV status and for those who tested negative early in pregnancy but are at increased risk of HIV infection and were not retested in the third trimester (AII). Testing should be available 24 hours a day, and results should be available within 1 hour. If results are positive, intrapartum antiretroviral (ARV) prophylaxis should be initiated immediately (AI).
- Women who were not tested for HIV before or during labor should undergo expedited HIV antibody testing during the immediate postpartum period (or their newborns should undergo expedited HIV antibody testing) (AII).
- When a woman has a positive HIV test result during labor and delivery or postpartum, or when a newborn’s expedited antibody test is positive, an appropriate infant ARV drug regimen should be initiated immediately, and the mother should not breastfeed while awaiting the results of supplemental HIV testing (AII). See Antiretroviral Management of Newborns with Perinatal HIV Exposure or Perinatal HIV for guidance.
- Results of maternal HIV testing should be documented in the newborn’s medical record and communicated to the newborn’s primary care provider (AIII).
- HIV testing is recommended for infants and children in foster care and adoptees for whom maternal HIV status is unknown, to identify perinatal HIV exposure and possible HIV infection (AIII), see Diagnosis of HIV Infections in Infants and Children.

### Rating of Recommendations: A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials in children† with clinical outcomes and/or validated endpoints; I* = One or more randomized trials in adults with clinical outcomes and/or validated laboratory endpoints with accompanying data in children† from one or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; II = One or more well-designed, nonrandomized trials or observational cohort studies in children† with long-term outcomes; II* = One or more well-designed, nonrandomized trials or observational studies in adults with long-term clinical outcomes with accompanying data in children† from one or more similar nonrandomized trials or cohort studies with clinical outcome data; III = Expert opinion

†Studies that include children or children and adolescents, but not studies limited to post-pubertal adolescents
### Panel’s Recommendations

- Discuss reproductive desires with all women of childbearing age on an ongoing basis throughout the course of their care (AIII).
- Provide information about effective and appropriate contraceptive methods to reduce the likelihood of unplanned pregnancy (AI).
- During preconception counseling, provide information on safe sex and encourage the elimination of alcohol, tobacco, and other drugs of abuse. With the increasing prevalence of the opioid epidemic, if elimination is not feasible, clinicians should provide appropriate treatment (e.g., methadone or buprenorphine) or counsel patients on how to manage health risks (e.g., access to a syringe services program) (AII).
- Women with HIV should attain maximum viral suppression before attempting conception for their own health to prevent sexual HIV transmission to partners without HIV (AI) and to minimize the risk of in utero HIV transmission to the infant (AI).
- When selecting or evaluating an antiretroviral (ARV) regimen for women of childbearing age with HIV, consider a regimen’s effectiveness, a woman’s hepatitis B status, the teratogenic potential of the drugs in the ARV regimen, and the possible adverse outcomes for the mother and fetus (AII). See Teratogenicity and Recommendations for Use of Antiretroviral Drugs During Pregnancy for more information. The Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission emphasizes the importance of counseling and shared decision making regarding all ARV regimens for people with HIV (AIII).
- HIV infection does not preclude the use of any contraceptive method; however, drug-drug interactions between hormonal contraceptives, antiretrovirals, and other medications should be considered (see Table 3) (AII).

**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
Reproductive Options for Couples When One or Both Partners Have HIV

(Revised December 29, 2020; last reviewed December 29, 2020)

Panel's Recommendations

For Couples Who Want to Conceive When One or Both Partners Have HIV:

- Expert consultation is recommended to tailor guidance to couples’ specific needs (AIII).
- Both partners should be screened and treated for genital tract infections before attempting to conceive (AI).
- Partners with HIV should achieve sustained viral suppression (e.g., two recorded measurements of plasma viral loads that are below the limits of detection at least 3 months apart) before attempting conception to maximize their health, prevent HIV sexual transmission (AI) and, for pregnant persons with HIV, to minimize the risk of HIV transmission to the infant (AI).
- When partners have different HIV statuses, sexual intercourse without a condom allows conception with effectively no risk of sexual HIV transmission to the partner without HIV if the partner with HIV is on antiretroviral therapy (ART) and has achieved sustained viral suppression (BII).
- Additional guidance might be required in the following scenarios:
  - The partner with HIV has not achieved sustained viral suppression or the partner’s HIV viral suppression status is unknown,
  - There are concerns that the partner with HIV might be inconsistently adherent to ART during the periconception period, or
  - The provider wishes to share additional information with the patient regarding options to prevent sexual HIV transmission during the periconception period.
- In these circumstances, providers can choose to counsel their patient about the following options:
  - Administration of antiretroviral pre-exposure prophylaxis (PrEP) to the partner without HIV reduces the risk of sexual acquisition of HIV (AI) see [Pre-exposure Prophylaxis (PrEP) to Reduce the Risk of Acquiring HIV During Periconception, Antepartum, and Postpartum Periods.]
  - Timing condomless sex to coincide with ovulation (peak fertility) is an approach that can optimize the probability of conception (AIII).
  - When partners with different HIV statuses attempt conception, the partner without HIV can choose to take PrEP even if the partner with HIV has achieved viral suppression (CIII).

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
Antepartum Care (Last updated December 29, 2020; last reviewed December 29, 2020)

General Principles Regarding Use of Antiretroviral Drugs During Pregnancy

Panel's Recommendations

- Initial evaluation of pregnant women with HIV should include an assessment of HIV disease status and plans to initiate, continue, or modify antiretroviral therapy (ART) (AI). The National Perinatal HIV Hotline (1-888-448-8765) provides free clinical consultation on all aspects of perinatal HIV care.
- All pregnant women with HIV should initiate ART as early in pregnancy as possible, regardless of their HIV RNA level or CD4 T lymphocyte count, to maximize their health and prevent perinatal HIV transmission and secondary sexual transmission (AI). Women with HIV should maintain an HIV viral load that is below the limit of detection during pregnancy, postpartum, and throughout their lives (AII).
- To minimize the risk of perinatal transmission, women with HIV should receive ART throughout pregnancy (including the intrapartum period), and neonates should receive appropriate antiretroviral (ARV) drugs (AI). See Recommendations for Use of Antiretroviral Drugs During Pregnancy and Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection.
- Women with HIV should be counseled on the known benefits and potential risks of all medications, including ARV drugs used during pregnancy and postpartum, as well as the importance of ART adherence. (AIII).
- ARV drug-resistance genotype evaluations or assays should be performed before starting ARV drug regimens in women who are ARV-naive (AII) or ARV-experienced (AIII) and before modifying ARV drug regimens (AII) in women whose HIV RNA levels are above the threshold for resistance testing (i.e., >500 copies/mL to 1,000 copies/mL).
- In pregnant women who are not already receiving ART, ART should be initiated before results of drug-resistance testing are available, because earlier viral suppression has been associated with lower risk of transmission. When ART is initiated before results are available, the regimen should be modified, if necessary, based on resistance assay results (BIII).
- Coordination of services among prenatal care providers, primary care and HIV specialty care providers, and, when appropriate, mental health and substance use disorder treatment services, intimate partner violence support services, and public assistance programs is essential to help ensure that women with HIV adhere to their ARV drug regimens (AII).
- Providers should initiate counseling about key intrapartum and postpartum considerations during pregnancy, including mode of delivery, lifelong HIV therapy, family planning and contraceptive options, infant feeding, infant ARV prophylaxis, and timing of infant diagnostic testing (AIII).

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
Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States

**Teratogenicity**

*(Last updated December 29, 2020; last reviewed December 29, 2020)*

### Panel’s Recommendations

- All cases of antiretroviral (ARV) drug exposure during pregnancy should be reported to the [Antiretroviral Pregnancy Registry](#) *(AIII)*.

- Based on multiple studies indicating no difference in rates of total birth defects for first-trimester exposure compared with later ARV drug exposures, women can be counseled that ARV drugs during pregnancy generally do not increase the risk of birth defects *(BIII)*; a possible exception is a very small potentially increased risk of neural tube defects (NTDs) with dolutegravir (DTG) use during the periconception period. Providers should be aware that data on the risks of birth defects for many ARV drugs are limited and evolving.

- Currently, in the United States there are not enough data to determine the risk of NTDs with preconception use of many of the Preferred and Alternative regimens, including DTG.

- DTG exposure around the time of conception has been associated with a small but significant increase in the prevalence of infant NTDs in Botswana, where food is not routinely fortified with folate. Although this prevalence of NTDs with periconception DTG (0.19%) was higher than the prevalence for NTDs in infants born to women who were receiving efavirenz (0.07%) and women without HIV (0.07%), the risk was not significantly increased compared to women with HIV receiving any non-DTG ARV regimen at conception (0.11%, risk difference [0.09% difference; 95% CI 0.03%, 0.30%]).

- Based on the available evidence, the Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission (the Panel) recommends DTG as a Preferred drug for pregnant women, irrespective of trimester *(AII)*, and for women who are trying to conceive *(AIII)*.

- The Panel emphasizes the importance of counseling and informed decision-making regarding all ARV regimens for people with HIV *(AIII)*. For additional information, see [Appendix C: Antiretroviral Counseling Guide for Health Care Providers: Pregnant Women and Women who are Trying to Conceive](#).

- Clinicians should discuss future reproductive plans and timing, as well as the risks and benefits of conceiving on specific ARV medications and the use of appropriate contraceptive options to prevent unintended pregnancy *(AIII)*.

- Folic acid is known to prevent NTDs in the general population. All pregnant women and women who might conceive should take at least 400 mcg of folic acid daily *(AI)*. For additional information, see [Recommendations for Use of Antiretroviral Drugs During Pregnancy, Preconception Counseling and Care for Women of Childbearing Age with HIV, Pregnant Women with HIV Who Are Currently Receiving Antiretroviral Therapy](#).

### 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
Panel's Recommendations

• Clinicians should be aware of a possible increased risk of adverse neonatal outcomes (e.g., preterm delivery) in pregnant women who are receiving antiretroviral therapy (ART). However, given the clear benefits of ART for both a woman’s health and the prevention of perinatal transmission, HIV treatment should not be withheld due to concern for adverse pregnancy outcomes (AII).

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

Recommendations for Use of Antiretroviral Drugs During Pregnancy: Overview

Panel’s Recommendations

• When choosing an antiretroviral (ARV) drug regimen for a pregnant woman, providers and patients should consider multiple factors, including adverse effects, drug interactions, pharmacokinetics (PKs), convenience of the individual drugs and drug combinations in the regimen, available pregnancy safety and outcome data, and the patient’s resistance test results and comorbidities (AIII).
• The same regimens that are recommended for the treatment of nonpregnant adults should be used in pregnant women when sufficient data suggest that appropriate drug exposure is achieved during pregnancy; clinicians should weigh the risks of adverse effects for women, fetuses, or infants against the benefits of these regimens and recognize that there are often incomplete data on the safety of ARV drugs in pregnancy (AII). For more information, see Tables 4 and 5.
• In most cases, women who present for obstetric care on fully suppressive ARV regimens should continue their current regimens (AIII).
• PK changes in pregnancy may lead to lower plasma levels of some ARV drugs and necessitate increased doses, more frequent dosing, boosting, more frequent viral load monitoring, or a change in ARV regimen; see Pregnant Women with HIV Who Are Currently Receiving Antiretroviral Therapy (AII).
• The Panel emphasizes the importance of counseling and informed decision-making regarding all ARV regimens for people with HIV (AIII). For additional information, see Preconception Counseling and Care for Women of Childbearing Age with HIV, Teratogenicity, Appendix C: Antiretroviral Counseling Guide for Health Care Providers, and Tables 4 and 5.
• After delivery, clinicians should discuss reproductive desires, the risks and benefits of conceiving on the current ARV regimen, and contraceptive options (AIII). See Preconception Counseling and Postpartum Care for more information.
• Folic acid is known to prevent neural tube defects in the general population. All pregnant women and women who might conceive should take at least 400 mcg of folic acid daily (AII).

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
Pregnant People with HIV Who Have Never Received Antiretroviral Drugs (Antiretroviral Naive)
(Last updated February 10, 2021; last reviewed February 10, 2021)

### Panel’s Recommendations

- Antiretroviral therapy (ART) is recommended for all pregnant people with HIV to reduce the risk of perinatal HIV transmission and to optimize the health of the pregnant person (AI). Initiating ART as soon as possible in pregnant people who have never received antiretroviral (ARV) drugs is recommended, based on data demonstrating that earlier virologic suppression is associated with a lower risk of transmission (AII).
- The results of HIV drug-resistance studies should guide the selection of ARV regimens in people whose HIV RNA levels are above the threshold for resistance testing (i.e., >500 copies/mL to 1,000 copies/mL), unless drug-resistance studies have been performed (see Antiretroviral Drug Resistance and Resistance Testing in Pregnancy) (AII). When ART is initiated before the results of the drug-resistance assays are available, the ARV regimen should be modified, if necessary, based on the resistance assay results (BIII).
- ARV regimens that are Preferred for the treatment of pregnant people with HIV who are ARV-naive include a dual-nucleoside reverse transcriptase inhibitor combination (abacavir plus lamivudine or tenofovir disoproxil fumarate plus either emtricitabine or lamivudine) and either a ritonavir-boosted protease inhibitor (atazanavir/ritonavir or darunavir/ritonavir) or an integrase strand transfer inhibitor (dolutegravir [irrespective of trimester] or raltegravir; see Table 4 and Recommendations for Use of Antiretroviral Drugs During Pregnancy) (AIII).
- The Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission emphasizes the importance of counseling and informed decision making, with regard to all ARV regimens for people with HIV (AIII). See Appendix C: Antiretroviral Counseling Guide for Health Care Providers for more information.

**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
Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States

(Pregnant Women with HIV Who Are Currently Receiving Antiretroviral Therapy
(Last updated February 10, 2021; last reviewed February 10, 2021)

Panel’s Recommendations

- Women with HIV who are receiving antiretroviral therapy (ART) and who present for pregnancy care should continue their ART during pregnancy, provided that the regimen is tolerated, safe, and effective in suppressing viral replication (defined as a regimen that maintains an HIV viral load less than lower limits of detection of the assay) (AII).
- When considering changes in ART during pregnancy, the Panel recommends patient counseling to support informed decision making. See Appendix C: Antiretroviral Counseling Guide for Health Care Providers.
- Women who present during pregnancy on drugs that are not recommended for use because of toxicity (e.g., stavudine, didanosine) should stop taking these drugs and be switched to other antiretroviral (ARV) drugs that are recommended for use during pregnancy (AIII). See Table 5 for more information.
- No data exist on the use of two-drug regimens during pregnancy (e.g., dolutegravir [DTG] plus lamivudine, DTG plus rilpivirine); women who present to care on one of these regimens should switch regimens or add additional ARV agents to these regimens.
- The use of atazanavir/cobicistat, darunavir/cobicistat, or elvitegravir/cobicistat regimens during pregnancy is associated with lower plasma drug exposures due to physiologic changes associated with pregnancy. These lower drug exposures pose an increased risk of virologic failure during the second and third trimesters of pregnancy (see Table 4 and Table 5). When a pregnant woman presents to care on one of these regimens, providers should decide whether to continue the regimen or to switch to a more effective regimen that is recommended for use in pregnant women (BIII). If one of these regimens is continued, absorption should be optimized by taking the drugs with food, and viral load should be monitored frequently (i.e., every 1–2 months).
- If an ARV regimen is altered during pregnancy, drugs in the new regimen should include ARV drugs that are recommended for use in pregnancy (see Table 4 and Table 5) (BIII), and more frequent virologic monitoring is warranted (CIII).
- ARV drug-resistance testing should be performed to assist the selection of active drugs when changing ARV regimens in pregnant women who are experiencing virologic failure on ART and who have HIV RNA levels >500 copies/mL to 1,000 copies/mL (AII). In individuals who have HIV RNA levels >500 copies/mL but <1,000 copies/mL, testing may be unsuccessful but still should be considered (BII). See Women Who Have Not Achieved Viral Suppression on Antiretroviral Therapy for more information.
- Clinicians should discuss future reproductive plans and timing, the risks and benefits of conceiving on specific ARV medications, and use of appropriate contraceptive options to prevent unintended pregnancy (AIII).

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
Pregnant Women with HIV Who Have Previously Received Antiretroviral Medications but are Not Currently Receiving Any Antiretroviral Medications

(Last updated December 29, 2020; last reviewed December 29, 2020)

<table>
<thead>
<tr>
<th>Panel's Recommendations</th>
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<tbody>
<tr>
<td>• Obtain an accurate history of all prior antiretroviral (ARV) medications used for HIV treatment or prevention of HIV transmission, including virologic efficacy, patient's tolerance of the medications, results of prior resistance testing, and problems with adherence (AIII).</td>
</tr>
<tr>
<td>• Choose and initiate an antiretroviral therapy (ART) regimen based on results of prior resistance testing, prior ARV drug use, concurrent medical conditions, and current recommendations for ART in pregnancy (see Table 5) (AII).</td>
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<tr>
<td>• If HIV RNA is above the threshold for standard genotypic drug resistance testing (i.e., &gt;500 to 1,000 copies/mL), ARV drug-resistance testing should be performed prior to starting an ARV drug regimen (see Antiretroviral Drug Resistance and Resistance Testing in Pregnancy) (AIII).</td>
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<tr>
<td>• ART should be initiated prior to receiving results of current ARV resistance assays. ART should be modified based on the results of the resistance assay, if necessary (BIII).</td>
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<tr>
<td>• If the ART regimen results in insufficient viral suppression, repeat resistance testing and assess other considerations, including adherence, food requirements, and drug interactions (AII).</td>
</tr>
<tr>
<td>• Consider consulting with an HIV treatment specialist when choosing an ART regimen for women who previously received ARV drugs or modifying ART for those who are not fully suppressed (BIII).</td>
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</tbody>
</table>

**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
Panel’s Recommendations

• The plasma HIV RNA levels of pregnant women with HIV should be monitored at the initial antenatal visit (AI), 2 to 4 weeks after initiating (or changing) antiretroviral therapy (ART) (BI), monthly until RNA levels are undetectable (BIII), and then at least every 3 months during pregnancy (BIII). HIV RNA levels also should be assessed at approximately 34 to 36 weeks gestation to inform decisions about mode of delivery (see Intrapartum Care for Women with HIV and to inform decisions about optimal management for the newborn (see Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection) (AIII).

• CD4 T lymphocyte (CD4) cell count should be measured at the initial antenatal visit (AI). Patients who have been on ART for ≥2 years and who have had consistent viral suppression and CD4 counts that are consistently >300 cells/mm³ do not need to have their CD4 counts monitored after the initial antenatal visit during this pregnancy, per the Adult and Adolescent Antiretroviral Guidelines (CIII). Women who have been on ART for <2 years, women with CD4 counts <300 cells/mm³, and women with inconsistent adherence and/or detectable viral loads should have CD4 counts monitored every 3 months during pregnancy (CIII).

• HIV drug-resistance testing (genotypic testing and, if indicated, phenotypic testing) should be performed in women whose HIV RNA levels are above the threshold for standard resistance testing (i.e., >500 copies/mL to 1,000 copies/mL) before—
  • Initiating ART in antiretroviral (ARV)-naive pregnant women who have not been previously tested for ARV drug resistance (AII);
  • Initiating ART in ARV-experienced pregnant women (AIII); or
  • Modifying ARV regimens for women who become pregnant while receiving ARV drugs or women who have suboptimal virologic response to ARV drugs that were started during pregnancy (AII).

• ART should be initiated in pregnant women prior to receiving the results of ARV-resistance tests. ART should be modified, if necessary, based on the results of resistance testing (BIII).

• Laboratory testing to monitor complications of ARV drugs during pregnancy should be based on what is known about the adverse effects of the drugs a woman is receiving (AIII).

• Women who are taking ART during pregnancy should undergo standard glucose screening (AIII). Some experts suggest performing glucose screening early in pregnancy for women who are receiving protease inhibitor (PI)-based regimens that were initiated before pregnancy, in accordance with recommendations for women who are at risk for glucose intolerance (BIII). For more information on PIs, see Combination Antiretroviral Drug Regimens and Maternal and Neonatal Outcomes.

• Amniocentesis, if clinically indicated, should be performed on women with HIV only after initiation of an effective ARV regimen and, ideally, when HIV RNA levels are undetectable (BIII). If a woman with detectable HIV RNA levels requires amniocentesis, consultation with an expert in the management of HIV during pregnancy should be considered (BIII).

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
Panel's Recommendations

- HIV drug-resistance testing (genotypic and, if indicated, phenotypic) should be performed in women living with HIV whose HIV RNA levels are above the threshold for resistance testing (i.e., >500 to 1,000 copies/mL) before:
  - Initiating antiretroviral therapy (ART) in antiretroviral (ARV)-naive pregnant women who have not been previously tested for ARV resistance (AII),
  - Initiating ART in ARV-experienced pregnant women (including those who have received pre-exposure prophylaxis) (AIII), or
  - Modifying ARV regimens for women who are newly pregnant and receiving ARV drugs or who have suboptimal virologic response to the ARV drugs started during pregnancy (AII).

- Phenotypic resistance testing is indicated for treatment-experienced persons on failing regimens who are thought to have multidrug resistance (BIII).

- ART should be initiated in pregnant women prior to receiving results of ARV-resistance testing; ART should be modified, if necessary, based on the results of resistance assays (BIII).

- If the use of an integrase strand transfer inhibitor (INSTI) is being considered and INSTI resistance is a concern, providers should supplement standard resistance testing with a specific INSTI genotypic resistance assay (BIII). INSTI resistance may be a concern if:
  - A patient received prior treatment that included an INSTI, or
  - A patient has a history with a sexual partner on INSTI therapy.

- Documented zidovudine (ZDV) resistance does not affect the indications for use of intrapartum intravenous ZDV (see Intrapartum Care for Women with HIV) (BIII).

- Choice of ARV regimen for an infant born to a woman with known or suspected drug resistance should be determined in consultation with a pediatric HIV specialist, preferably before delivery (see Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection) (AIII).

- Pregnant women living with HIV should be given ART to maximally suppress viral replication, which is the most effective strategy for preventing development of resistance and minimizing risk of perinatal transmission (AII).

- All pregnant and postpartum women should be counseled about the importance of adherence to prescribed ARV medications to reduce the risk of developing resistance (AII).

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
Women Who Have Not Achieved Viral Suppression on Antiretroviral Therapy
(Last updated December 29, 2020; last reviewed December 29, 2020)

Panel’s Recommendations

- Because maternal antenatal viral load correlates with the risk of perinatal transmission of HIV, suppression of HIV RNA to undetectable levels should be achieved as rapidly as possible (AII).
- For pregnant women who have not achieved viral suppression (after an adequate period of treatment):
  - Assess medication adherence, tolerability, dosing, potential problems with absorption, adherence to food requirements, and possible drug interactions.
  - If HIV RNA is >500 copies/mL, perform tests for resistance (AII).
  - Consult an HIV treatment expert and consider possible antiretroviral regimen modification (AIII).
- Please see Intrapartum Care for Women with HIV with HIV for guidance about use of intrapartum intravenous zidovudine prophylaxis and scheduled cesarean delivery for women who have not achieved viral suppression on ART (AII).

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

Stopping Antiretroviral Drugs During Pregnancy
(Last updated December 29, 2020; last reviewed December 29, 2020)

Panel’s Recommendations

- If an antiretroviral (ARV) drug regimen must be stopped during pregnancy (e.g., for severe toxicity), all ARV drugs should be stopped simultaneously, and a complete, effective ARV regimen should be reinitiated as soon as possible (AIII).

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
### Panel’s Recommendations

- All pregnant women with HIV should be screened during the current pregnancy for:
  - Hepatitis B virus (HBV) infection, unless they are already known to have HBV/HIV coinfection or have serologic documentation of HBV immunity, and
  - Hepatitis C virus (HCV) infection, unless they are already known to have HCV/HIV coinfection (see [Hepatitis C Virus/HIV Coinfection](#) (AIII)).

- All pregnant women with HIV who screen negative for HBV infection and lack HBV immunity (i.e., HBV surface antigen negative, HBV core antibody negative, and HBV surface antibody negative) should promptly receive the HBV vaccine series (AII).
- Women with chronic HBV infection who have not already received the hepatitis A virus (HAV) vaccine series should be screened for immunity to HAV. If they screen negative for HAV antibodies (either IgG or total antibody [IgG and IgM]), they should receive the HAV vaccine series (AIII).
- All pregnant and postpartum women with HBV/HIV coinfection should receive antiretroviral therapy (ART) that includes tenofovir disoproxil fumarate (TDF) or tenofovir alafenamide (TAF) plus lamivudine or emtricitabine (AII).
- Pregnant women with HBV/HIV coinfection who are receiving ART should be counseled about signs and symptoms of liver toxicity, and liver transaminases should be assessed 1 month after initiating ART and at least every 3 months thereafter during pregnancy (BIII).
- During and after pregnancy, women with chronic HBV should be counseled on the importance of continuing anti-HBV medications indefinitely. If ART that includes medications with anti-HBV activity is discontinued in women with HBV/HIV coinfection, frequent monitoring of liver function tests for potential exacerbation of HBV infection is recommended, with prompt re-initiation of treatment for HBV when a flare is suspected (BIII).
- Decisions concerning mode of delivery of the infant in a pregnant woman with HBV/HIV coinfection should be based on standard obstetric and HIV-related indications alone; HBV/HIV coinfection is not an indication for cesarean delivery (see [Intrapartum Care for Women with HIV](#) (AIII)).
- Within 12 hours of birth, infants born to women with HBV should receive hepatitis B immune globulin and the first dose of the HBV vaccine series (AI).

### 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
### Special Populations: Hepatitis C Virus/HIV Coinfection

(Updated December 29, 2020; last reviewed December 29, 2020)

#### Panel's Recommendations

- All pregnant women with HIV should be screened during the current pregnancy for hepatitis C virus (HCV) infection (AIII).
  - HCV screening should be repeated later in pregnancy in women who initially screen negative for HCV but who have persistent or new risk factors for HCV (e.g., new or ongoing injection or intranasal substance use) (AIII).
- All pregnant women with HIV should also be tested for hepatitis B virus (HBV) infection (see Hepatitis B Virus/HIV Coinfection) (AII).
- Women with HCV infection who have not already received the hepatitis A virus (HAV) vaccine series should be screened for immunity to HAV (AIII). If they screen negative for HAV antibodies (either IgG or total antibody (IgG and IgM)), they should receive the HAV vaccine series (AIII).
- All pregnant women with HIV (with or without HCV) who screen negative for HBV infection and lack HBV immunity (i.e., HBV surface antigen negative, HBV core antibody negative, and HBV surface antibody negative) should receive the HBV vaccine series (AII).
- Currently, treatment of HCV during pregnancy is not recommended (unless part of an approved experimental protocol) because of the lack of safety data on the use of HCV direct-acting antiviral medications in pregnant women. If considering initiating HCV treatment in a pregnant woman with HIV coinfection, consultation with an expert in HIV and HCV is strongly recommended (AIII).
- Recommendations for antiretroviral therapy (ART) during pregnancy are the same for all women with HIV, including those who have HCV coinfection (AIII).
- Pregnant women with HCV/HIV coinfection who are receiving ART should be counseled about the signs and symptoms of liver toxicity, and hepatic transaminases should be assessed 1 month following initiation of ART and at least every 3 months thereafter during pregnancy (BIII).
- Women with HCV should be strongly considered for HCV treatment with direct-acting antiviral agents (DAAs) postpartum (AI).
- In women who have tested positive for HCV, 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).
- Decisions concerning the mode of infant delivery in pregnant women with HCV/HIV coinfection should be based on standard obstetric and HIV-related indications alone; HCV coinfection does not necessitate cesarean delivery when not otherwise indicated (see Intrapartum Care for Women with HIV (AIII).
- Infants born to women with HCV/HIV coinfection should be evaluated for HCV infection (AIII). Decisions regarding the specific type of assays to use for HCV screening in children and the timing of those assays should be made after consultation with an expert in pediatric HCV infection (AIII).

#### 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
### Panel’s Recommendations

- **HIV-2 infection** should be considered in pregnant women who are from—or who have partners who are from—countries in which the virus is endemic and who have positive results on an HIV-1/HIV-2 antibody or HIV-1/HIV-2 antigen/antibody immunoassay. They should be tested with a supplemental HIV-1/HIV-2 antibody differentiation assay. If they have only HIV-2 infection, the test will be negative for HIV-1 antibodies and positive for HIV-2 antibodies (AII).

- Pregnant women with HIV-2 should be treated as per guidelines for HIV-1 mono-infection but using antiretroviral (ARV) drugs that are active against HIV-2. Non-nucleoside reverse transcriptase inhibitors and enfuvirtide are not active against HIV-2 and should not be used (AIII).

- No randomized clinical trials have been performed to address when to start treatment or what the optimal treatment is for HIV-2 infection (AIII). A regimen with two nucleoside reverse transcriptase inhibitors (NRTIs) and integrase strand transfer inhibitors or certain boosted protease inhibitors is recommended for all pregnant women with HIV-2 infection (AIII).

- Dolutegravir (irrespective of trimester), raltegravir, darunavir/ritonavir, or lopinavir/ritonavir plus a dual-NRTI backbone of abacavir plus lamivudine (3TC), or tenofovir disoproxil fumarate (TDF) plus emtricitabine or 3TC are recommended for treating HIV-2 mono-infection in pregnant women and in women trying to conceive (AIII). Zidovudine (ZDV) plus 3TC can be used as an alternative dual-NRTI backbone. See Updated Panel Recommendations Regarding the Use of Dolutegravir in Pregnancy in Recommendations for Use of Antiretroviral Drugs During Pregnancy and Appendix C: Antiretroviral Counseling Guide for Health Care Providers: Pregnant Women and Women who are Trying to Conceive.

- As with HIV-1, the possibility of hepatitis B virus/HIV-2 coinfection should be considered when choosing an ARV regimen to treat HIV-2 (AI) (see Hepatitis B Virus/HIV Coinfection).

- All infants born to women with HIV-2 infection (who do not have HIV-1 infection) should receive the 4-week ZDV prophylactic regimen (BIII).

- In the United States, where safe infant formula is readily available, breastfeeding is not recommended for infants born to mothers with HIV-2 infection (AIII).

### 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
**Panel’s Recommendations**

- The management of prenatal care and general principles of antiretroviral therapy (ART) and HIV management do not differ between pregnant women with perinatally acquired HIV (PHIV) and those with nonperinatally acquired HIV *(AII)*.
- Using the same guiding principles that are used for heavily ART-experienced adults, optimal ART regimens should be selected based on resistance testing, ART treatment history, and pill burden *(AII)*.
- Consultation with experts in HIV and pregnancy is recommended when the presence of extensive drug resistance warrants the use of antiretroviral drugs for which there is limited experience in pregnancy *(AIII)*.
- Pregnant women with PHIV warrant enhanced focus on adherence interventions during pregnancy and after delivery *(AII)*.

**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
Panel’s Recommendations

- When acute HIV infection is suspected in pregnancy or during breastfeeding, a plasma HIV RNA test should be obtained in conjunction an antigen/antibody immunoassay test (see Acute and Recent [Early] HIV Infection in the Adult and Adolescent Antiretroviral Guidelines and the Centers for Disease Control and Prevention HIV testing algorithm for more information) (AII).
- Repeat HIV testing in the third trimester is recommended for pregnant women with initial negative HIV test results who are known to be at risk of acquiring HIV, who are receiving care in facilities that have an HIV incidence of ≥1 case per 1,000 pregnant women per year, who reside in jurisdictions with elevated HIV incidence, or who reside in states that require third-trimester testing (see Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings) (AII).
- All pregnant women with acute or recent HIV infection should start antiretroviral therapy (ART) as soon as possible to prevent perinatal transmission, with the goal of rapidly suppressing plasma HIV RNA below detectable levels (AI).
- In women with acute HIV infection, baseline genotypic resistance testing should be performed simultaneously with initiation of ART (AII), and the regimen should be adjusted, if necessary, to optimize virologic response (BIII).
- Dolutegravir plus tenofovir disoproxil fumarate (TDF) plus emtricitabine (FTC) is the Preferred ART regimen for pregnant women, irrespective of trimester, and for breastfeeding women with acute HIV (see Table 4, Table 5, Recommendations for Use of Antiretroviral Drugs During Pregnancy, and Appendix C: Antiretroviral Counseling Guide) (AII).
  - Raltegravir plus TDF plus FTC or a ritonavir-boosted protease inhibitor (either atazanavir ATV/r or darunavir/r) plus TDF plus FTC are Alternative ART regimens for pregnant and breastfeeding women with acute HIV (AIII). See Table 4, Table 5, and Recommendations for Use of Antiretroviral Drugs During Pregnancy for more information.
- The Panel on Treatment of Pregnant Women with HIV Infection 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).
- Lactating women who receive a diagnosis of acute HIV infection should be counseled to discontinue breastfeeding.
- Infants born to women who received a diagnosis of acute 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 6 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 (see Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection).

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
**Intrapartum Care for Women with HIV**  
*(Last updated December 29, 2020; last reviewed December 29, 2020)*

### Panel’s Recommendations

#### HIV Testing for Women with Unknown HIV Status in Labor
- Women who present in labor with unknown HIV status and women with increased risk of HIV infection who were not retested in the third trimester should undergo expedited antigen/antibody HIV testing *(AII)*. See Maternal HIV Testing and Identification of Perinatal HIV Exposure for more information.
  - If results are positive, an HIV-1/HIV-2 antibody differentiation test and an HIV-1 RNA assay should be done as soon as possible, and intravenous (IV) zidovudine (ZDV) should be initiated pending the result of the differentiation test *(AII)*.
  - If acute HIV infection is suspected or if a woman has had recent HIV exposure, an HIV RNA assay should be done at the time of expedited antigen/antibody testing *(AII)*. See Acute HIV Infection.

#### Intrapartum Antiretroviral Therapy (ART), Zidovudine (ZDV) Prophylaxis, and Mode of Delivery for Women with HIV

- **For women with HIV RNA >1,000 copies/mL or unknown HIV RNA near the time of delivery (≥34 to 36 weeks gestation or 4 to 6 weeks before delivery):**
  - Intrapartum IV ZDV should be administered in the following situations based on laboratory and clinical information near the time of delivery: (a) HIV RNA >1,000 copies/mL, (b) unknown HIV RNA, (c) a suspected lack of adherence since the last HIV RNA result, or (d) a positive expedited antigen/antibody HIV test result during labor *(AI)*. Begin IV ZDV when women present in labor or at least 3 hours prior to scheduled cesarean delivery *(AII)*.
  - When HIV RNA is >1,000 copies/mL or is unknown near the time of delivery, scheduled cesarean delivery at 38 weeks gestation is recommended to minimize perinatal HIV transmission, irrespective of administration of antepartum ART *(AII)*.
  - Management of women originally scheduled for cesarean delivery because of HIV RNA >1,000 copies/mL who present in labor or with ruptured membranes must be individualized at the time of presentation *(BII)*. In these circumstances, evidence is insufficient to determine whether cesarean delivery reduces the risk of perinatal HIV transmission. Consultation with an expert in perinatal HIV (e.g., telephone consultation with the National Perinatal HIV/AIDS Clinical Consultation Center at 1-888-448-8765) may be helpful in rapidly developing an individualized delivery plan.
  - **For women receiving ART with HIV RNA ≤1,000 copies/mL near the time of delivery (≥34 to 36 weeks gestation or 4 to 6 weeks before delivery):**
    - IV ZDV is not required for women who meet **ALL** of the following three criteria: (1) are receiving ART, (2) have HIV RNA <50 copies/mL at ≥34 to 36 weeks gestation (or 4–6 weeks before delivery), and (3) are adherent to their antiretroviral (ARV) regimen *(BII)*.
    - IV ZDV may be considered for women with HIV RNA ≥50 copies/mL and ≤1,000 copies/mL near delivery (≥34 to 36 weeks gestation) *(BII)*. Data are insufficient to determine whether administration of IV ZDV to women with HIV RNA levels between 50 copies/mL and 1,000 copies/mL provides any additional protection against perinatal HIV transmission. This decision can be made on a case-by-case basis, taking into consideration the woman’s recent ART adherence and her preferences and involving expert consultation if needed *(CII)*.
    - Scheduled cesarean delivery performed solely for prevention of perinatal HIV transmission in women receiving ART with HIV RNA ≤1,000 copies/mL near the time of delivery is **not recommended** given the low rate of perinatal transmission in this group *(AII)*.
    - In women with HIV RNA levels ≤1,000 copies/mL, if scheduled cesarean delivery or induction of labor is indicated for non-HIV-related reasons, it should be performed at the standard time for obstetric indications *(AII)*. Labor should not be induced to prevent perinatal HIV transmission.
• In women on ART with HIV RNA ≤1,000 copies/mL, duration of ruptured membranes is not associated with an increased risk of perinatal transmission and is not an indication for cesarean delivery to prevent HIV transmission (BII).

**Other Intrapartum Management Considerations (see Table 7 below).**

• Fetal scalp electrodes for fetal monitoring should be avoided, particularly when maternal HIV RNA is not suppressed (≥50 copies/mL) or is unknown, because of the potential risk of HIV transmission (BIII). See Antiretroviral Management of Newborns with Perinatal HIV Exposure or Perinatal HIV.

• Artificial rupture of membranes (ROM) and operative vaginal delivery with forceps or a vacuum extractor should follow standard obstetric indications but should be avoided if possible in women with HIV RNA ≥50 copies/mL (BIII).

• The ARV regimen a woman is receiving should be taken into consideration when using methergine to treat excessive postpartum bleeding caused by uterine atony.

• In women who are receiving a cytochrome P450 (CYP) 3A4 enzyme inhibitor (e.g., a protease inhibitor or cobicistat), methergine should be used only if no alternative treatments for postpartum hemorrhage are available and the need for pharmacologic treatment outweighs the risks. If methergine is used, it should be administered at the lowest effective dose for the shortest possible duration (BIII).

• In women who are receiving a CYP3A4 enzyme inducer—such as nevirapine, efavirenz, or etravirine—additional uterotonic agents may be needed because of the potential for decreased methergine levels and inadequate treatment effect (BIII).

**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
Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States

Counseling and Managing Women with HIV in the United States Who Desire to Breastfeed (Last updated, February 10, 2021; last reviewed February 10, 2021)

Panel’s Recommendations

- Antiretroviral therapy (ART) is currently recommended for all individuals with HIV to reduce the risk of disease progression and to prevent the sexual transmission of HIV (AI).
- ART should be continued after delivery (AI). Any plans for modifying ART after delivery should be made in consultation with the woman and her HIV care provider, ideally before delivery, taking into consideration the recommended regimens for nonpregnant adults (AII) and plans for future pregnancies.
- Because the immediate postpartum period poses unique challenges to ART adherence, arrangements for new or continued supportive services should be made before hospital discharge (AI).
- Women with a positive rapid HIV antibody test during labor require immediate linkage to HIV care and comprehensive follow-up, including for confirmation of HIV infection (AI).
- Prior to hospital discharge, the woman should be given ART for herself and her newborn to take at home (AIII).
- Breastfeeding is not recommended for women in the United States who have confirmed HIV or are presumed to have HIV, because safer infant feeding alternatives are available (AI). 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.
- Infant feeding counseling, including a discussion of potential barriers to formula feeding, should begin during the prenatal period, and this information should be reviewed after delivery (AIII).
- Clinicians should discuss future reproductive plans and timing, as well as the risks and benefits of conceiving on specific antiretroviral (ARV) medications and the use of appropriate contraceptive options to prevent unintended pregnancy (AIII).
- Contraceptive counseling should involve shared decision-making and should start during the prenatal period; a contraceptive plan should be developed prior to hospital discharge, as desired by the patient (AIII).

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

Counseling and Managing Women with HIV in the United States Who Desire to Breastfeed (Last updated, February 10, 2021; last reviewed February 10, 2021)

Panel’s Recommendations

- In the United States, formula feeding is the strategy least likely to result in HIV transmission, because breastfeeding presents an ongoing risk of HIV exposure after birth, and because suppressive maternal antiretroviral therapy significantly reduces but does not eliminate the risk of transmitting HIV through breastfeeding. Therefore, breastfeeding is not recommended for women with HIV in the United States (AI).
- Women who have questions about breastfeeding or who desire to breastfeed should receive patient-centered, evidence-based counseling on infant feeding options (AIII).
- When women with HIV choose to breastfeed, they should be supported in risk-reduction measures to minimize the risk of HIV transmission to their infants (BIII).

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
# Panel’s Recommendations

- All newborns who were exposed perinatally to HIV should receive postpartum antiretroviral (ARV) drugs to reduce the risk of perinatal transmission of HIV (AI).
- Newborn ARV regimens administered at doses that are appropriate for the infant’s gestational age should be initiated as close to the time of birth as possible, preferably within 6 hours of delivery (AII).
- A newborn’s ARV regimen should be determined based on maternal and infant factors that influence the risk of perinatal transmission of HIV (AII). The uses of ARV regimens in newborns include:
  - **ARV Prophylaxis:** The administration of one or more ARV drugs to a newborn without documented HIV infection to reduce the risk of perinatal acquisition of HIV.
  - **Presumptive HIV Therapy:** The administration of a three-drug ARV regimen to newborns who are at highest risk of perinatal acquisition of HIV. Presumptive HIV therapy is intended to be preliminary treatment for a newborn who is later documented to have HIV, but it also serves as prophylaxis against HIV acquisition for those newborns who are exposed to HIV in utero, during the birthing process, or during breastfeeding and who do not acquire HIV.
  - **HIV Therapy:** The administration of a three-drug ARV regimen at treatment doses (called antiretroviral therapy [ART]) to newborns with documented HIV infection (see Diagnosis of HIV Infection in Infants and Children).

A 4-week zidovudine (ZDV) ARV prophylaxis regimen can be used in newborns whose mothers received ART during pregnancy and had viral suppression near delivery (defined as a confirmed HIV RNA level <50 copies/mL) and for whom maternal adherence is not of concern (BII).

Newborns at high risk of perinatal acquisition of HIV should begin presumptive HIV therapy (see Table 9 for recommended regimens). Newborns at high risk of HIV acquisition include those born to women with HIV who—
- Have not received antepartum or intrapartum ARV drugs (AI), or
- Have received only intrapartum ARV drugs (AI), or
- Have received antepartum ARV drugs but who did not achieve viral suppression (defined as a confirmed HIV RNA level <50 copies/mL) near delivery (AII), or
- Have primary or acute HIV infection during pregnancy (AII), or
- Have primary or acute HIV infection while breastfeeding (AII).

If a woman presents with unknown HIV status and has a positive expedited HIV test during labor or shortly after delivery, the infant should begin presumptive HIV therapy (AII). If supplemental maternal testing is negative, the infant’s ARV regimen should be discontinued (AII).

For newborns with HIV infection, ART should be initiated (AI).

- The use of ARV drugs other than ZDV, lamivudine, and nevirapine cannot be recommended for any indication in premature newborns (<37 weeks gestational age) because of the lack of dosing and safety data (BII).

Providers with questions about ARV management of perinatal HIV exposure should consult the National Perinatal HIV Hotline (1-888-448-8765), which provides free clinical consultation on all aspects of perinatal HIV, including newborn care (AIII).

**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
### Panel’s Recommendations

- **Virologic assays** (i.e., HIV RNA or HIV DNA nucleic acid tests [NATs]) that directly detect HIV must be used to diagnose HIV in infants and children aged <18 months with perinatal and postnatal HIV exposure; HIV antibody tests should not be used (AII).
- **Plasma HIV RNA or cell-associated HIV DNA NATs** are generally equally recommended (AII). However, the results of plasma HIV RNA NAT or plasma HIV RNA/DNA NAT can be affected by antiretroviral therapy (ART).
- An assay that detects HIV non-B subtype viruses or Group O infections (e.g., an HIV RNA NAT or a dual-target total DNA/RNA test) is recommended for use in infants and children who were born to mothers with known or suspected non-B subtype virus or Group O infections (AII). If a mother of an infant acquired HIV outside of the United States and has had repeated undetectable HIV RNA by standard testing, consultation with a clinical virologist on more sensitive HIV nucleic acid testing may be indicated.
- Virologic diagnostic testing (see Figure 1 and 2) is recommended for all infants with perinatal HIV exposure at the following ages:
  - 14 to 21 days (AII)
  - 1 to 2 months (AII)
  - 4 to 6 months (AII)
- For infants who are at high risk of perinatal HIV infection, additional virologic diagnostic testing is recommended at birth (AII) and at 2 to 6 weeks after antiretroviral (ARV) drugs are discontinued (BII).
- A positive virologic test should be confirmed as soon as possible by repeat virologic testing (AII).
- Definitive exclusion of HIV infection in non-breastfed infants is based on two or more negative virologic tests, with one obtained at age ≥1 month and one at age ≥4 months, or two negative HIV antibody tests from separate specimens that were obtained at age ≥6 months (AII).
- Some experts confirm the absence of HIV at age 12 to 18 months in children with prior negative virologic tests by performing an HIV antibody test to document loss of maternal HIV antibodies (BIII).
- Since children aged 18 to 24 months with perinatal HIV exposure occasionally have residual maternal HIV antibodies, definitive exclusion or confirmation of HIV infection in children in this age group who remain HIV antibody-positive should be based on an HIV NAT (AII).
- Diagnostic testing in children with non-perinatal exposure only or in children with perinatal exposure aged >24 months relies primarily on the use of HIV antibody (or antigen/antibody) tests.
- When acute HIV infection is suspected, additional testing with an HIV NAT may be necessary to diagnose HIV infection (AII).

**Note:** The National Clinician Consultation Center provides consultations on issues related to the management of perinatal HIV infection (1-888-448-8765; 24 hours a day, 7 days a week).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials in children† with clinical outcomes and/or validated endpoints; I* = One or more randomized trials in adults with clinical outcomes and/or validated laboratory endpoints with accompanying data in children† from one or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; II = One or more well-designed, nonrandomized trials or observational cohort studies in children† with long-term outcomes; II* = One or more well-designed, nonrandomized trials or observational studies in adults with long-term clinical outcomes with accompanying data in children† from one or more similar nonrandomized trials or cohort studies with clinical outcome data; III = Expert opinion

† Studies that include children or children/adolescents, but not studies limited to post-pubertal adolescents
Initial Postnatal Management of the Neonate Exposed to HIV
(Last updated December 29, 2020; last reviewed December 29, 2020)

Panel’s Recommendations

• All newborns who were perinatally exposed to HIV should receive appropriate antiretroviral (ARV) drugs as soon as possible after delivery (see Antiretroviral Management of Newborns with Perinatal HIV Exposure or Perinatal HIV (AI)).
• A complete blood count and differential should be performed on newborns as a baseline evaluation (BIII).
• Infants who are found to have hematologic abnormalities may need to discontinue ARV drugs. Clinicians should base the decision to discontinue ARV drugs on the individual needs of the patient. Consultation with an expert in pediatric HIV infection is advised if early discontinuation of ARV drugs is considered (CIII).
• When determining the timing for subsequent monitoring of hematologic parameters in infants, clinicians need to consider the infant’s baseline hematologic values, gestational age at birth, and clinical condition; whether the infant is receiving zidovudine (ZDV), other ARV drugs, or certain concomitant medications; and the specific ARV drugs used in the mother’s antepartum drug regimen (CIII).
• Hemoglobin and neutrophil counts should be remeasured 4 weeks after initiating an ARV regimen that contains ZDV and lamivudine (AI).
• Virologic tests are required to diagnose HIV infection in infants aged <18 months (see Diagnosis of HIV Infection in Infants and Children (AI)).
• To prevent Pneumocystis jirovecii pneumonia (PCP), all infants born to women with HIV should begin PCP prophylaxis at ages 4 to 6 weeks, after completing their ARV prophylaxis or an empiric HIV therapy regimen, unless there is adequate test information to presumptively exclude HIV infection (see the Pediatric Opportunistic Infection Guidelines (AI)).
• Health care providers should routinely inquire about infant feeding plans and/or breastfeeding desires, as well as the use of premasticated (prechewed or prewarmed) food. Counseling against premastication and discussion of safe infant feeding options should be provided (see Counseling and Managing Women Living with HIV in the United States Who Desire to Breastfeed (AI)).

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

Long-Term Follow-Up of Infants Exposed to Antiretroviral Drugs
(Last updated December 29, 2020; last reviewed December 29, 2020)

Panel’s Recommendations

• Children with in utero or neonatal exposure to antiretroviral (ARV) drugs who develop significant organ system abnormalities of unknown etiology, particularly of the nervous system or heart, should be evaluated for potential mitochondrial dysfunction (CIII).
• It is important that the long-term medical record of a child without HIV includes information about in utero and neonatal ARV exposure (BIII).

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

*(Last updated December 29, 2020; last reviewed December 29, 2020)*

### Panel's Recommendations

- **Health care providers** should offer and promote oral combination tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) pre-exposure prophylaxis (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 (STI), 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.

- **People who become pregnant while using TDF/FTC as PrEP** can continue PrEP throughout their pregnancy. Risk for HIV acquisition should be reassessed and people should be counseled regarding benefits and risks of PrEP use in pregnancy *(AII)*.

- **Providers should counsel patients** about the benefits of PrEP to reduce the risk of maternal HIV acquisition and perinatal HIV transmission *(AI)* and about potential risks of PrEP to mother and fetus or infant during periconception, pregnancy, postpartum, and breastfeeding periods *(AII)*.

- **In cases when the individual’s risk factor is one identified partner with HIV and that partner is on antiretroviral therapy (ART) with sustained viral suppression**, PrEP may be optional because condomless sexual intercourse is associated with effectively no risk of sexual HIV transmission when HIV viral load is suppressed *(AI)* (see Reproductive Options for Couples When One or Both Partners Have HIV).

- **Providers should counsel patients** about the importance of daily adherence to oral PrEP in preventing HIV acquisition *(AI)*. Women should be counseled to take a once-daily pill of coformulated TDF/FTC PrEP for 20 days prior to being protected from HIV and therefore should use back-up protection in the interim *(BII)*. No data support on-demand PrEP use for people exposed to HIV through vaginal exposure.

- **Providers should offer routine PrEP follow-up**, including testing for HIV every 3 months and counseling on signs and symptoms of acute retroviral syndrome *(AI)* (see the Centers for Disease Prevention and Control Guidelines for HIV Pre-Exposure Prophylaxis and Maternal HIV Testing and Identification of Perinatal HIV Exposure). More frequent testing may be appropriate when clinically indicated (e.g., adherence challenges, nonstandard visit schedule).

Other novel PrEP agents including oral tenofovir alafenamide (TAF)/FTC and injectable agents are not yet recommended for people exposed to HIV through receptive vaginal sex.

### 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**