



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

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# Maternal HIV Testing and Identification of Perinatal HIV Exposure

(Last updated April 16, 2019; last reviewed April 16, 2019)

## Panel's Recommendations

- HIV testing is recommended as standard of care for all sexually active women and should be a routine component of preconception care **(AII)**.
- All pregnant 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](#)) **(AII)**.
- Partners of pregnant women should be encouraged to undergo 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 who are receiving care in facilities that have an HIV incidence of  $\geq 1$  case per 1,000 pregnant women per year, those who reside in jurisdictions with elevated HIV incidence, or those 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)**.
- Expedited HIV testing at the time of labor or delivery should be performed for any woman with undocumented HIV status; testing should be available 24 hours a day, and results should be available within 1 hour **(AII)**. If results are positive, intrapartum antiretroviral (ARV) prophylaxis should be initiated immediately **(AI)**, and infants should receive an ARV regimen that is appropriate for infants who are at higher risk of perinatal HIV transmission as soon as possible, pending results of supplemental HIV testing **(AII)**. See [Antiretroviral Management of Newborns with Perinatal HIV Exposure or Perinatal HIV](#) for guidance.
- Women who have not been 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)**. If the results for the mother or infant are positive, an appropriate infant ARV drug regimen should be initiated immediately, and the mother should not breastfeed unless supplemental HIV testing is negative **(AII)**. Infants with initial positive HIV viral tests (RNA, DNA) should have their ARV regimen modified, if necessary, to a three-drug combination of ARV drugs at treatment doses (see [Antiretroviral Management of Newborns with Perinatal HIV Exposure or Perinatal HIV](#)) **(AII)**.
- 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 to determine HIV status is recommended for infants and children in foster care and adoptees for whom maternal HIV status is unknown **(AIII)**.

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

**Rating of Evidence:** I = One or more randomized trials in children<sup>†</sup> 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<sup>†</sup> 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<sup>†</sup> 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<sup>†</sup> from one or more similar nonrandomized trials or cohort studies with clinical outcome data; III = Expert opinion

<sup>†</sup> Studies that include children or children/adolescents, but not studies limited to post-pubertal adolescents

# Preconception Counseling and Care for Women of Childbearing Age Living with HIV (Last updated December 7, 2018; last reviewed December 7, 2018)

## 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; 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., use of syringe services program) (AII).
- All women living with HIV who are contemplating pregnancy should be receiving antiretroviral therapy (ART) and have a plasma viral load below the limit of detection prior to conception (AII).
- When selecting or evaluating ART for women of childbearing age living with HIV, consider a regimen's effectiveness, a woman's hepatitis B status, teratogenic potential of the drugs in the ART regimen, and possible adverse outcomes for the mother and fetus (AII).
- HIV infection does not preclude the use of any contraceptive method; however, drug-drug interactions between hormonal contraceptives and ART should be considered (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 in Which One or Both Partners are Living with HIV (Last updated December 7, 2018; last reviewed December 7, 2018)

## Panel's Recommendations

For Couples Who Want to Conceive When One or Both Partners are Living with HIV:

- Expert consultation is recommended to tailor guidance to couples' specific needs (AIII).
- Partners should be screened and treated for genital tract infections before attempting to conceive (AII).
- Partners living with HIV should attain maximum viral suppression before attempting conception to prevent HIV sexual transmission (AI) and, for women living with HIV, to minimize the risk of HIV transmission to the infant (AII).
- For couples with differing HIV statuses, **when the partner living with HIV is on ART and has achieved sustained viral suppression**, sexual intercourse without a condom limited to the 2 to 3 days before and the day of ovulation (peak fertility) is an approach to conception with **effectively no risk** of sexual HIV transmission to the partner without HIV (BII).
- For couples with differing HIV statuses who attempt conception via sexual intercourse without a condom (despite counseling) **when the partner living with HIV has not been able to achieve viral suppression or when the viral suppression status is not known**, administration of antiretroviral pre-exposure prophylaxis (PrEP) to the partner without HIV is recommended to reduce the risk of sexual transmission of HIV (AI). Couples should still be counseled to limit sex (without condoms) to the period of peak fertility (AIII).
- When the woman is living with HIV, assisted insemination at home or in a provider's office with semen **from a partner without HIV** during the periovulatory period is **an option for** conception that eliminates the risk of HIV transmission to the partner without HIV (AIII).
- When the man is living with HIV, the use of donor sperm from a man without HIV **is an option for** conception that eliminates the risk of HIV transmission to the partner without HIV (BIII).
- For couples with differing HIV statuses who attempt conception (sexual intercourse without a condom limited to peak fertility) when the partner living with HIV has achieved viral suppression, it is unclear whether administering PrEP to the partner without HIV further reduces the risk of sexual transmission (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 7, 2018; last reviewed December 7, 2018)

### Panel's Recommendations

- Initial evaluation of pregnant women living 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 (888-448-8765) provides free clinical consultation on all aspects of perinatal HIV care.
- All pregnant women living with HIV should initiate ART as early in pregnancy as possible, regardless of their plasma HIV RNA copy number or CD4 T lymphocyte count, to prevent perinatal transmission **(AI)**. It is recommended that the HIV viral load be maintained below the limit of detection throughout pregnancy and lifetime of the individual living with HIV **(AII)**.
- To minimize the risk of perinatal transmission, antiretroviral (ARV) drugs should be administered at all time points (including antepartum and intrapartum) to the woman as well as postnatally to the neonate **(AI)**.
- The known benefits and potential risks of all medications, including ARV drugs used during pregnancy and postpartum, should be discussed with all women living with HIV **(AIII)**.
- The importance of adherence to ARV drug regimens should be emphasized during patient counseling **(AII)**.
- ARV drug-resistance genotype studies 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 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**. If 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 drug abuse treatment services, intimate partner violence support services, and public assistance programs is essential to help ensure that women living 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, maternal lifelong HIV therapy, family planning and contraceptive options, infant feeding, infant ARV prophylaxis, timing of infant diagnostic testing, and neonatal circumcision **(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

## Teratogenicity (Last updated December 7, 2018; last reviewed December 7, 2018)

### Panel's Recommendations

- All cases of antiretroviral (ARV) drug exposure during pregnancy should be reported to the [Antiretroviral Pregnancy Registry \(AIII\)](#).
- Based on the preponderance of studies indicating no difference in rates of birth defects for first-trimester exposure compared with later ARV drug exposures, women can be counseled that ARV therapy during pregnancy generally does not increase the risk of birth defects (BIII), with the possible exception of dolutegravir.

#### Interim Panel Recommendations Regarding the Use of Dolutegravir at the Time of Conception and During Pregnancy:<sup>a</sup>

- Dolutegravir **is not recommended for use in nonpregnant women who are trying to conceive or during the first trimester of pregnancy**,<sup>b,c</sup> due to concerns about a possible increased risk of neural tube defects (NTDs) (AIII).
- Clinicians should discuss the possible increased risk of NTDs with women of childbearing potential who are currently receiving dolutegravir as part of their ART or who wish to be started on dolutegravir (AIII).
- A pregnancy test should be performed prior to the initiation of dolutegravir (AIII).
- Women who want to become pregnant or who cannot consistently use effective contraception should not initiate a dolutegravir-based regimen (AIII).
- For pregnant women who are receiving dolutegravir and who present to care during the first trimester,<sup>b,c</sup> provide counseling about the risks and benefits of continuing dolutegravir or switching to another ARV regimen (AIII). The following considerations should be addressed:
  - NTDs may have already occurred;
  - Depending on the current gestational age, the additional risk of NTDs developing during the remaining time in first trimester may be small;
  - There is a background risk of NTDs regardless of antiretroviral treatment (ART) regimen or HIV status (this risk ranges from 0.05% to 0.1% for women without HIV, and women with HIV who are receiving ART that does not include dolutegravir); *and*
  - Changes in ART, even in the first trimester, are often associated with viral rebound that may increase the risk of perinatal HIV transmission.
- Dolutegravir is a preferred integrase strand transfer inhibitor for use in pregnant women after the first trimester;<sup>b</sup> this designation is based on available PK, safety, and efficacy data (AII).
- When dolutegravir use is continued after delivery, clinicians should recommend the use of postpartum contraception and discuss contraceptive options with patients (AIII).
- For additional information, see Interim Recommendations about the Use of Dolutegravir in Pregnancy in [Recommendations for the Use of Antiretroviral Drugs During Pregnancy](#) and the [Adult and Adolescent Antiretroviral Guidelines](#).

**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

<sup>a</sup> These are intended to be conservative, interim recommendations and will be revised, if indicated, as additional data become available in 2019.

<sup>b</sup> The first trimester is less than 14 weeks (up to 13 6/7 weeks) gestational age by last menstrual period. The term "12 weeks post-conception," used in the Adult and Adolescent ARV Guidelines, is consistent with the first trimester.

<sup>c</sup> Although dolutegravir is not Food and Drug Administration-approved for use in the first trimester, some Perinatal Panel members would consider using dolutegravir at 12 weeks gestational age by last menstrual period on an individual patient basis.

## ***Combination Antiretroviral Drug Regimens and Maternal and Neonatal Outcomes***

**(Last updated December 7, 2018; last reviewed December 7, 2018)**

### **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. However, given the clear benefits of such regimens for both a woman's health and the prevention of perinatal transmission, HIV treatment should not be withheld for fear of altering 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 (Last updated December 7, 2018; last reviewed December 7, 2018)

### Panel's Recommendations

- Multiple factors must be considered when choosing an antiretroviral (ARV) drug regimen for a pregnant woman. These factors include the adverse effects, drug interactions, pharmacokinetics (PKs), convenience of individual drugs and drug combinations in the regimen, experience with the use of these drugs in pregnancy, and the patient's resistance test results and comorbidities (AIII).
- In general, 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, unless there are known adverse effects for women, fetuses, or infants that outweigh the benefits if these regimens (AII).
- 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 drugs and necessitate increased dosages, more frequent dosing, boosting, or more frequent viral load monitoring (AII).

#### Interim Panel Recommendations Regarding the Use of Dolutegravir in Pregnancy:<sup>a</sup>

- Dolutegravir **is not recommended** for use in pregnant women **during the first trimester**<sup>b,c</sup> and in **nonpregnant women who are trying to conceive**, due to concerns about a possible increased risk of neural tube defects (NTDs) (AIII).
- Dolutegravir is a preferred integrase strand transfer inhibitor for use in pregnant women after the first trimester;<sup>b</sup> this designation is based on available PK, safety, and efficacy data (AII).
- For pregnant women who are receiving dolutegravir and who present to care during the first trimester,<sup>b,c</sup> provide counseling about the risks and benefits of continuing dolutegravir or switching to another ARV regimen (AIII). The following considerations should be addressed:
  - NTDs may have already occurred;
  - Depending on the current gestational age, the additional risk of NTDs developing during the remaining time in first trimester may be small;
  - There is a background risk of NTDs regardless of antiretroviral treatment (ART) regimen or HIV status (this risk ranges from 0.05% to 0.1% for women without HIV, and women with HIV who are receiving ART that does not include dolutegravir); *and*
  - Changes in ART, even in the first trimester, are often associated with viral rebound that may increase the risk of perinatal HIV transmission.
- When dolutegravir use is continued after delivery, clinicians should recommend the use of postpartum contraception and discuss contraceptive options with patients (AIII).
- For additional information, see subsection below for Interim Guidance about the Use of Dolutegravir in Pregnancy and [Teratogenicity](#).

**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

<sup>a</sup> These are intended to be conservative, interim recommendations and will be revised, if indicated, as additional data become available in 2019.

<sup>b</sup> The first trimester is less than 14 weeks (up to 13 6/7 weeks) gestational age by last menstrual period. The term "12 weeks post-conception," used in the Adult and Adolescent ARV Guidelines, is consistent with the first trimester.

<sup>c</sup> Although dolutegravir is not Food and Drug Administration-approved for use in the first trimester, some Perinatal Panel members would consider using dolutegravir at 12 weeks gestational age by last menstrual period on an individual patient basis.

## Pregnant Women Living with HIV Who Have Never Received Antiretroviral Drugs (Antiretroviral Naive) (Last updated December 7, 2018; last reviewed December 7, 2018)

### Panel's Recommendations

- Antiretroviral therapy (ART) is recommended for all pregnant women living with HIV to reduce the risk of perinatal transmission of HIV and to optimize the health of the mother (AI). Initiation of ART as soon as HIV is diagnosed during pregnancy is recommended, based on data demonstrating that earlier virologic suppression is associated with a lower risk of transmission (AII).
- HIV drug-resistance studies should guide the selection of ART regimens in women whose HIV RNA levels are above the threshold for resistance testing (i.e., >500 to 1000 copies/mL), unless drug-resistance studies have already 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).
- The choice of regimen should be informed by current adult treatment guidelines; what is known about the use of specific drugs in pregnancy; the risk of teratogenicity (see [Table 6](#) and [Table 10](#)); and maternal factors such as nausea, vomiting, and comorbid conditions. ART regimens that are preferred for the treatment of pregnant women living with HIV who are ARV-naive include: a dual nucleoside reverse transcriptase inhibitor combination (abacavir/lamivudine or tenofovir disoproxil fumarate/emtricitabine or lamivudine) and either a ritonavir-boosted protease inhibitor (atazanavir/ritonavir or darunavir/ritonavir) or an integrase strand transfer inhibitor (dolutegravir [after the first trimester]<sup>a</sup> or raltegravir) (see [Table 6](#) and [Interim Panel Recommendations Regarding the Use of Dolutegravir in Pregnancy in Recommendations for the Use of Antiretroviral Drugs During Pregnancy](#)) (AIII).
- Dolutegravir **is not recommended** for use in pregnant women during the first trimester<sup>a,b</sup> and in nonpregnant women who are trying to conceive, due to concerns about a possible increased risk of neural tube defects (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

<sup>a</sup> The first trimester is <14 weeks (up to 13 6/7 weeks) gestational age by last menstrual period. The term "12 weeks post-conception," used in the Adult and Adolescent Antiretroviral Guidelines, is consistent with the first trimester.

<sup>b</sup> Although dolutegravir is not Food and Drug Administration-approved for use in the first trimester, some Panel members would consider using dolutegravir at 12 weeks gestational age by last menstrual period on an individual patient basis.



## Pregnant Women Living with HIV Who Are Currently Receiving Antiretroviral Therapy (Last updated December 7, 2018; last reviewed December 7, 2018)

### Panel's Recommendations

- Women living with HIV who are receiving antiretroviral therapy (ART) who present for pregnancy care should continue their ART during pregnancy, provided that the regimen is tolerated, safe, and effective in suppressing viral replication (i.e., HIV viral load less than lower limits of detection of the assay) (AII).
- Drugs that are not recommended for use because of toxicity (e.g., stavudine, didanosine) should be stopped and switched to another antiretroviral (ARV) drug in women who present during pregnancy on these medications (AIII), see [Table 7](#).
- Women who are receiving a dolutegravir-containing regimen and who present to care in the first trimester should receive counseling about the possible increased risk of neural tube defects (NTDs) and the risks and benefits of continuing dolutegravir or switching to another ARV regimen (AIII)<sup>a,b</sup> (see Interim Recommendations about the Use of Dolutegravir in Pregnancy in [Recommendations for the Use of Antiretroviral Drugs During Pregnancy](#) and [Table 7](#)). The following considerations should be addressed:
  - NTDs may have already occurred;
  - Depending on the current gestational age, the additional risk of NTDs developing during the remaining time in the first trimester may be small;
  - There is a background risk of NTDs regardless of antiretroviral treatment (ART) regimen or HIV status (this risk ranges from 0.05% to 0.1% for women without HIV and for women with HIV who are receiving ART that does not include dolutegravir); and
  - Changes in ART, even in the first trimester, are often associated with viral rebound that may increase the risk of perinatal HIV transmission.
- When women present to care on a atazanavir/cobicistat-, darunavir/cobicistat-, or elvitegravir/cobicistat-containing regimen, providers should consider switching to a regimen that is recommended for use in pregnant women due to concerns about pharmacokinetic changes and risk of virologic failure in the second and third trimesters of pregnancy (see [Table 6](#) and [Table 7](#)) (BIII). If one of these regimens is continued, absorption should be optimized, 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 be ARVs recommended for use in pregnancy (see [Table 6](#) and [Table 7](#)) (BIII) and more frequent virologic monitoring is warranted (CIII).
- HIV ARV drug-resistance testing should be performed to assist in the selection of active drugs when changing ARV regimens in pregnant women on therapy with virologic failure and HIV RNA levels >500 to 1,000 copies/mL (AII). In individuals with HIV RNA levels >500 but <1,000 copies/mL, testing may be unsuccessful but should still be considered (BII) (see [Lack of Viral Suppression](#)).

**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

<sup>a</sup> The first trimester is less than 14 weeks (up to 13 6/7 weeks) gestational age by last menstrual period. The term “12 weeks post-conception,” used in the Adult and Adolescent ARV Guidelines, is consistent with the first trimester.

<sup>b</sup> Although dolutegravir is not Food and Drug Administration–approved for use in the first trimester, some Perinatal Panel members would consider using dolutegravir at 12 weeks gestational age by last menstrual period on an individual patient basis.

## Pregnant Women Living with HIV Who Have Previously Received Antiretroviral Treatment or Prophylaxis but Are Not Currently Receiving Any Antiretroviral Medications (Last updated December 7, 2018; last reviewed December 7, 2018)

### Panel's Recommendations

- Obtain an accurate history of all prior antiretroviral (ARV) regimens used for treatment of HIV disease or prevention of transmission, including virologic efficacy, the patient's tolerance of the medications, results of prior resistance testing, and problems with adherence (AIII).
- Choose and initiate a combination antiretroviral therapy (ART) regimen based on results of prior resistance testing, prior ARV use, concurrent medical conditions, and current recommendations for ART in pregnancy, avoiding drugs with potential known adverse effects for the mother or fetus/infant (see [Table 7](#)) (AII).
- If HIV RNA is above the threshold for resistance testing (i.e., >500 to 1,000 copies/mL), ARV resistance testing should be performed prior to starting an ARV drug regimen (see [Antiretroviral Drug Resistance and Resistance Testing in Pregnancy](#)) (AIII).
- In general, ART should be initiated prior to receiving results of current ARV resistance studies, because longer use of ART during pregnancy has been associated with reduced transmission rates to the infant compared to shorter treatment periods. ART should be modified based on the results of the resistance assay, if necessary (BIII).
- If the ART regimen results in insufficient viral suppression, repeat resistance testing and assess other considerations, including adherence, food requirements, and drug interactions (AII).
- Consider consulting with an HIV treatment specialist about the choice of ART regimen to initiate in women who previously received ARV drugs or to modify ART in those who are not fully suppressed (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

## Monitoring of the Woman and Fetus During Pregnancy (Last updated December 7, 2018; last reviewed December 7, 2018)

### Panel's Recommendations

- 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 (ARV) drug regimens (**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 [Transmission and Mode of Delivery](#)) and to inform decisions about optimal treatment for the newborn (see [Antiretroviral Management of Newborns](#)) (**AIII**).
- CD4 T lymphocyte (CD4) cell count should be monitored at the initial antenatal visit (**AI**). For patients who have been on antiretroviral therapy (ART) for  $\geq 2$  years and who have had consistent viral suppression and CD4 cell counts that are consistently  $>300$  cells/mm<sup>3</sup>, CD4 cell count should be monitored at the initial antenatal visit; CD4 cell counts do not have to be repeated for these patients during this pregnancy, per the [Adult and Adolescent Antiretroviral Guidelines](#) (**CIII**). Women who have been on ART for  $<2$  years, women with CD4 cell counts  $<300$  cells/mm<sup>3</sup>, and women with inconsistent adherence and/or detectable viral loads should have CD4 cell counts monitored every 3 to 6 months during pregnancy (**CIII**).
- HIV drug-resistance testing should be performed in women whose HIV RNA levels are above the threshold for resistance testing (i.e.,  $>500$  copies/mL to 1,000 copies/mL) before:
  - Initiating ART in ARV-naïve pregnant women who have not been previously tested for ARV resistance (**AII**);
  - Initiating ART in ARV-experienced pregnant women (**AIII**); or
  - Modifying ART regimens for women entering pregnancy while receiving ARV drugs or women who have suboptimal virologic response to ARV drugs started during pregnancy (**AII**).
- ART should be initiated in pregnant women prior to receiving results of ARV-resistance tests. ART should be modified, if necessary, based on the results of the resistance assay (**BIII**).
- Monitoring for 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 taking ART during pregnancy should undergo standard glucose screening at 24 to 28 weeks' gestation (**AIII**). Some experts suggest glucose screening early in pregnancy for women who are receiving protease inhibitor (PI)-based regimens 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](#).
- An ultrasound, performed as soon as possible, is recommended to confirm gestational age and, if scheduled cesarean delivery is necessary, to guide the timing of the procedure (see [Transmission and Mode of Delivery](#)) (**AII**).
- Amniocentesis, if clinically indicated, should be performed on women with HIV only after initiation of an effective ART regimen and, ideally, when HIV RNA levels are undetectable (**BIII**). In women with detectable HIV RNA levels in whom amniocentesis is deemed necessary, consultation with an expert in the management of HIV in 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

## Antiretroviral Drug Resistance and Resistance Testing in Pregnancy (Last updated December 7, 2018; last reviewed December 7, 2018)

### Panel's Recommendations

- HIV drug-resistance **genotype** studies 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 (**AIII**), or
  - Modifying ART regimens for women who are entering pregnancy while receiving ARV drugs or who have suboptimal virologic response to ARV drugs started during pregnancy (**AII**).
- ART should be initiated in pregnant women prior to receiving results of ARV-resistance studies; ART should be modified, if necessary, based on the results of the resistance assay (**BIII**).
- If an integrase strand transfer inhibitor (INSTI) is being considered for an ART-naive patient 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 because:**
  - A patient received prior treatment that included an INSTI,
  - A patient has a history with a sexual partner on INSTI therapy, or
  - A patient is starting or changing ART regimen late in pregnancy, in which case an INSTI might be selected because of its ability to rapidly decrease viral load.
- Documented zidovudine resistance does not affect the indications for use of intrapartum zidovudine (**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 Perinatal HIV](#)) (**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 potential for development of 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

## Lack of Viral Suppression (Last updated December 7, 2018; last reviewed December 7, 2018)

### 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**).
- If an ultrasensitive HIV RNA assay indicates failure of viral suppression (after an adequate period of treatment):
  - If HIV RNA level is >500 copies/mL, assess medication adherence, **adherence to food requirements, and possible drug interactions** and perform tests for resistance (**AII**).
  - Consult an HIV treatment expert and consider possible antiretroviral regimen modification (**AIII**).
- Scheduled cesarean delivery at 38 weeks' gestation is recommended for pregnant women living with HIV who have HIV RNA levels >1,000 copies/mL near the time of 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

## Stopping Antiretroviral Drugs during Pregnancy (Last updated December 7, 2018; last reviewed December 7, 2018)

### 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 antiretroviral therapy 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

## Special Populations: Hepatitis B Virus/HIV Coinfection (Last updated December 7, 2018; last reviewed December 7, 2018)

### Panel's Recommendations

- All pregnant women living with HIV should be screened during the current pregnancy for
  1. Hepatitis B virus (HBV) infection, unless they are known to have HBV/HIV coinfection or serologic documentation of HBV immunity coinfection, and
  2. 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 living with HIV who screen negative for HBV (i.e., HBV surface antigen negative, HBV core antibody negative, and HBV surface antibody negative) should 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 immunoglobulin G antibody, they should receive the HAV vaccine series (AIII).
- All pregnant and postpartum women with HBV/HIV coinfection should receive antiretroviral therapy (ART). Antepartum ART in pregnant women with HBV/HIV coinfection should include tenofovir disoproxil fumarate (TDF) plus lamivudine or emtricitabine (AI). If a woman with HBV/HIV coinfection becomes pregnant while virally suppressed on an antiretroviral (ARV) regimen that includes tenofovir alafenamide (TAF) plus lamivudine or emtricitabine, she can be offered the choice of continuing that ART regimen or switching TAF to TDF in her ART regimen (BIII).
- Pregnant women with HBV/HIV coinfection who are receiving ARV drugs should be counseled about signs and symptoms of liver toxicity, and liver transaminases should be assessed 1 month following initiation of ART and at least every 3 months thereafter during pregnancy (BIII).
- Women with chronic HBV should be counseled on the importance of continuing anti-HBV medications indefinitely, both during and after pregnancy. If ARV drugs that include anti-HBV activity are 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 does not necessitate a cesarean delivery if not otherwise indicated (see [Transmission and Mode of Delivery](#)) (AIII).
- Within 12 hours of birth, infants born to women with HBV infection 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 (Last updated December 7, 2018; last reviewed December 7, 2018)

### Panel's Recommendations

- All pregnant women with HIV should be screened during the current pregnancy for
  1. Hepatitis B virus (HBV) infection, unless they are known to have HBV/HIV coinfection or serologic documentation of HBV immunity coinfection (see [Hepatitis B Virus/HIV Coinfection](#)), and
  2. Hepatitis C virus (HCV) infection unless they are known to have HCV/HIV coinfection (AIII).
- Women with HCV infection who have not already received the hepatitis A virus (HAV) vaccine series should be screened for immunity to HAV, because they are at increased risk of complications from coinfection with other viral hepatitis infections (AIII). If they screen negative for HAV antibodies (IgG or IgG plus IgM), they should receive the HAV vaccine series (AIII).
- All pregnant women with HIV and/or HCV who screen negative for HBV infection (i.e., HBV surface antigen negative and HBV core antibody negative) and lack HBV immunity (i.e., HBV surface antibody negative) should receive the HBV vaccine series (AII).
- When considering 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 living with HIV, whether they have HCV or not (AIII).
- Pregnant women with HCV/HIV coinfection who are receiving ART should be counseled about 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).
- 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 it is not otherwise indicated (see [Transmission and Mode of Delivery](#)) (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

## HIV-2 Infection and Pregnancy (Last updated December 7, 2018; last reviewed December 7, 2018)

### Panel's Recommendations

- HIV-2 infection should be considered in pregnant women who are from—or who have partners from—countries in which the disease 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 living with HIV-1/HIV-2 coinfection should be treated as per guidelines for HIV-1 monoinfection, but using antiretroviral drugs that are active against HIV-2 (see below).
- 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 and certain boosted protease inhibitors or integrase strand transfer inhibitors is recommended for all pregnant women living with HIV-2 infection (AIII).
- Non-nucleoside reverse transcriptase inhibitors and enfuvirtide are not active against HIV-2 and should not be used (AIII).
- All infants born to mothers living with HIV-2 infection should receive the 4-week zidovudine prophylactic regimen (BIII).
- In the United States, where safe infant formula is readily available, breastfeeding is not recommended for infants of mothers living 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

## The Management of Prenatal Care and General Principles of Antiretroviral Therapy and HIV Management in Women with Perinatal HIV Infection (Last updated December 7, 2018; last reviewed December 7, 2018)

### 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, prior ART 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 (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

## Acute HIV Infection (Last updated June 12, 2019; last reviewed December 7, 2018)

### Panel's Recommendations

- When acute HIV infection is suspected in pregnancy or during breastfeeding, a plasma HIV RNA test should be obtained in conjunction with a routine HIV antibody screening test or 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 (CDC) HIV testing algorithm for more information (AII).
- Repeat HIV testing in the third trimester is recommended for pregnant women with initial negative HIV antibody tests who are known to be at risk of acquiring HIV, who are receiving care in facilities that have an HIV incidence of  $\geq 1$  case per 1,000 pregnant women per year, or who reside in jurisdictions with elevated HIV incidence (see [Prenatal and Perinatal Human Immunodeficiency Virus Testing, Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings](#) and the CDC HIV testing algorithm) (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 suppressing plasma HIV RNA to 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).
- In pregnant and breastfeeding women with acute HIV infection, a dolutegravir-based regimen with tenofovir disoproxil fumarate plus emtricitabine should be initiated (after the first trimester<sup>a</sup> in pregnant women), and breastfeeding should be discontinued (see [Table 6](#)) (AII). Dolutegravir should not be initiated in women during the first trimester<sup>a,b</sup> of pregnancy due to concerns about a possible increased risk of neural tube defects (NTDs) (AIII).
- Alternatively, a ritonavir-boosted, protease inhibitor-based regimen can be initiated (AIII). See Interim Panel Recommendations Regarding the Use of Dolutegravir in Pregnancy in [Recommendations for the Use of Antiretroviral Drugs during Pregnancy](#).
- When dolutegravir use is continued after delivery, clinicians should recommend the use of postpartum contraception and discuss contraceptive options with patients (AIII).
- Infants born to women who received a diagnosis of acute HIV infection during pregnancy or breastfeeding are at high risk of perinatal HIV transmission and should receive an ARV regimen that is appropriate for this elevated risk (see [Table 8 in Antiretroviral Management of Newborns with Perinatal HIV Exposure or Perinatal HIV](#)) (AII). Consultation with a pediatric HIV specialist regarding appropriate infant management is strongly recommended (see [Antiretroviral Management of Newborns with Perinatal HIV Exposure or Perinatal HIV](#)).

**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

<sup>a</sup> The first trimester is less than 14 weeks (up to 13 6/7 weeks) gestational age by last menstrual period. The term "12 weeks post-conception," used in the Adult and Adolescent ARV Guidelines, is consistent with the first trimester.

<sup>b</sup> Although dolutegravir is not Food and Drug Administration-approved for use in the first trimester, some Perinatal Panel members would consider using dolutegravir at 12 weeks gestational age by last menstrual period on an individual patient basis.



## Intrapartum Care (Last updated December 7, 2018; last reviewed December 7, 2018)

### Panel's Recommendations

- Women should continue taking their antepartum combination antiretroviral therapy (ART) on schedule as much as possible during labor and before scheduled cesarean delivery (AIII).
- Intravenous (IV) zidovudine:
  - Should be administered to women living with HIV if HIV RNA is known or suspected to be >1,000 copies/mL (or if HIV RNA is unknown) near delivery (AI).
  - Is not required for women who are receiving ART regimens and who have HIV RNA ≤50 copies/mL during late pregnancy and near delivery and no concerns regarding adherence to the ART regimen (BII).
  - May be considered for women with HIV RNA between 50 and 999 copies/mL. There are inadequate data to determine whether administration of IV zidovudine to women with HIV RNA levels between 50 and 999 copies/mL provides any additional protection against perinatal transmission. This decision can be made on a case by case basis, taking into consideration the woman's recent ART adherence, her preferences, and involving expert consultation if needed (CII).
- Scheduled cesarean delivery at 38 weeks' gestation (compared to 39 weeks for most indications) is recommended for women who have HIV RNA >1,000 copies/mL near delivery (see [Transmission and Mode of Delivery](#)) (AI).
- Women who present in labor with unknown HIV status should undergo expedited antigen/antibody HIV testing (AII).
  - If the 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 maternal (IV zidovudine)/infant (combination antiretroviral [ARV] prophylaxis) ARV drugs should be initiated pending results of the differentiation test (AII).
  - If the maternal HIV differentiation test is positive or if acute infection is suspected because the differentiation test is negative but the HIV RNA test is positive, infant ARV drugs should be managed as discussed in [Antiretroviral Management of Newborns with Perinatal HIV Exposure or Perinatal HIV](#) (AI). Women with positive expedited testing should not initiate breastfeeding until HIV infection is definitively ruled out (see [Postpartum Follow-Up of Women Living with HIV Infection](#)) (AII).
  - If the maternal HIV differentiation test is negative and acute HIV infection has been reasonably excluded with a negative HIV RNA test, the maternal and infant ARV drugs should be stopped (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

## Transmission and Mode of Delivery (Last updated December 7, 2018; last reviewed December 7, 2018)

### Panel's Recommendations

- Scheduled cesarean delivery at 38 weeks gestation to minimize perinatal transmission of HIV is recommended for women with HIV RNA levels >1,000 copies/mL or unknown HIV levels near the time of delivery, irrespective of administration of antepartum antiretroviral therapy (ART) (**AII**).
- Scheduled cesarean delivery performed solely for prevention of perinatal transmission in women receiving ART with HIV RNA ≤1,000 copies/mL **is not routinely 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 is indicated, it should be performed at the standard time for obstetrical indications (**AII**).
- In women with an HIV RNA >1,000 copies/mL or unknown HIV RNA level who present in spontaneous labor or with ruptured membranes, there is insufficient evidence to determine whether cesarean delivery reduces the risk of perinatal HIV transmission. Management of women originally scheduled for cesarean delivery because of HIV who present in labor must be individualized at the time of presentation (**BII**). In these circumstances, consultation with an expert in perinatal HIV (e.g., telephone consultation with the National Perinatal HIV/AIDS Clinical Consultation Center at 888-448-8765) may be helpful in rapidly developing an individualized delivery plan.
- 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 vaginal delivery is recommended (**BII**).

**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

## Other Intrapartum Management Considerations (Last updated December 7, 2018; last reviewed December 7, 2018)

### Panel's Recommendations

- Artificial rupture of membranes (ROM) can be performed for standard obstetric indications in virologically suppressed women with HIV who are on antiretroviral therapy (ART) (**BII**).
- The following procedures should generally be avoided because of a potential increased risk of HIV perinatal transmission, unless there are clear obstetric indications:
  - Artificial ROM in the setting of viremia (**BIII**)
  - Routine use of fetal scalp electrodes for fetal monitoring (**BIII**)
  - Operative delivery with forceps or a vacuum extractor (**BIII**)
- The ART regimen a woman is receiving should be taken into consideration when treating excessive postpartum bleeding resulting from uterine atony:
  - In women who are receiving a cytochrome P450 (CYP) 3A4 enzyme inhibitor (e.g., a protease inhibitor, integrase inhibitor, 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 (**BII**).
  - 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

## Postpartum Care (Last updated December 7, 2018; last reviewed December 7, 2018)

### Panel's Recommendations

- Antiretroviral therapy (ART) is currently recommended for all individuals living with HIV to reduce the risk of disease progression and to prevent the sexual transmission of HIV (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 (AIII).
- Because the immediate postpartum period poses unique challenges to antiretroviral (ARV) adherence, arrangements for new or continued supportive services should be made before hospital discharge (AII).
- Contraceptive counseling should start during the prenatal period; a contraceptive plan should be developed prior to hospital discharge (AIII).
- Women with a positive rapid HIV antibody test during labor require immediate linkage to HIV care and comprehensive follow-up, including confirmation of HIV infection (AII).
- Prior to hospital discharge, the woman should be given ARV medications for herself and her newborn to take at home (AIII).
- Breastfeeding is not recommended for women in the United States with confirmed or presumed HIV infection, because safer alternatives are available (AI).
- 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).

**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

## Guidance for Counseling and Managing Women Living with HIV in the United States Who Desire to Breastfeed (Last updated December 7, 2018; last reviewed December 7, 2018)

### Panel's Recommendations

- Breastfeeding **is not recommended** for women living with HIV in the United States (AII).
- 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 despite intensive counseling, they should be counseled to use harm-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

## Antiretroviral Management of Newborns with Perinatal HIV Exposure or Perinatal HIV (Last Updated December 7, 2018; last reviewed December 7, 2018)

### Panel's Recommendations

- All newborns perinatally exposed to HIV should receive postpartum antiretroviral (ARV) drugs to reduce the risk of perinatal transmission of HIV (**AI**).
- Newborn ARV regimens—at gestational-age-appropriate doses—should be initiated as close to the time of birth as possible, preferably within 6 to 12 hours of delivery (**AII**).
- The selection of a newborn ARV regimen should be determined based on maternal and infant factors that influence risk of perinatal transmission of HIV (**AIII**). 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.
  - **Empiric HIV Therapy:** The administration of a three-drug ARV regimen to newborns at highest risk of perinatal acquisition of HIV. Empiric HIV therapy is intended to be preliminary treatment for a newborn who is later documented to have HIV but 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 dosages (antiretroviral therapy [ART]) to newborns with documented HIV infection (see [Diagnosis of HIV Infection](#)).
- For newborns whose mothers have received ART during pregnancy with sustained viral suppression near delivery and for whom there are no concerns related to maternal adherence, a 4-week zidovudine ARV prophylaxis regimen can be used (**BII**).
- Newborns at higher risk of perinatal acquisition of HIV should receive a multi-drug ARV prophylaxis regimen or empiric HIV therapy based on clinician assessment of risk (see [Tables 8](#) and [9](#) for recommended regimens). **Newborns at higher 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 without viral suppression near delivery (**AII**), *or*
  - Have primary or acute HIV infection during pregnancy (**AII**), *or*
  - Have primary or acute HIV infection during breastfeeding (**AII**).
- Newborns of women with unknown HIV status who test HIV positive on expedited testing performed during labor or shortly after birth should initiate an ARV regimen (ARV prophylaxis or empiric HIV therapy based on clinician assessment of risk) (**AII**). If supplemental testing is negative, the ARV regimen can be discontinued (**AII**).
- For newborns with HIV infection, ART should be initiated (**AI**).
- The use of ARV drugs other than zidovudine, lamivudine, and nevirapine cannot be recommended for any indication in premature newborns (<37 weeks gestational age) because of lack of dosing and safety data (**BIII**).
- 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

## Diagnosis of HIV Infection in Infants and Children (Last updated December 7, 2018; last reviewed December 7, 2018)

### Panel's Recommendations

- Virologic assays (i.e., HIV RNA and 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)**.
- HIV RNA or HIV DNA **NATs** are generally equally recommended **(AII)**.
- 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)**.
- Virologic diagnostic testing 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 at higher risk of perinatal HIV transmission, additional virologic diagnostic testing is recommended at birth **(AII)** and at 2 to 4 weeks after cessation of antiretroviral prophylaxis **(BII)**.
- A positive virologic test should be confirmed as soon as possible by a repeat virologic test on a second specimen **(AII)**.
- Definitive exclusion of HIV infection in nonbreastfed infants is based on two or more negative virologic tests, with one obtained at age  $\geq 1$  month and one at age  $\geq 4$  months, or two negative HIV antibody tests from separate specimens obtained at age  $\geq 6$  months **(AII)**.
- Some experts confirm the absence of HIV at 12 to 18 months of age 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 are HIV antibody-positive should be based on an HIV NAT **(AII)**.
- Diagnostic testing in children with nonperinatal exposure only or 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 **(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<sup>†</sup> 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<sup>†</sup> 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<sup>†</sup> 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<sup>†</sup> from one or more similar nonrandomized trials or cohort studies with clinical outcome data; III = Expert opinion

<sup>†</sup> Studies that include children or children and adolescents, but not studies limited to post-pubertal adolescents

## Initial Postnatal Management of the Neonate Exposed to HIV (Last updated December 7, 2018; last reviewed December 7, 2018)

### Panel's Recommendations

- A complete blood count and differential should be performed on newborns as a baseline evaluation (BIII).
- If hematologic abnormalities are identified in infants receiving prophylaxis, decisions on whether to continue infant antiretroviral (ARV) prophylaxis need to be individualized. Consultation with an expert in pediatric HIV infection is advised if early discontinuation of prophylaxis is considered (CIII).
- Decisions about the timing of subsequent monitoring of hematologic parameters in infants depend on the infant's baseline hematologic values, gestational age at birth, clinical condition, infant receipt of zidovudine, other ARV drugs, and concomitant medications; and maternal antepartum therapy (CIII).
- Hemoglobin and neutrophil counts should be remeasured 4 weeks after initiation of prophylaxis for infants who receive combination zidovudine/lamivudine-containing ARV prophylaxis regimens (AI).
- Routine measurement of serum lactate is not recommended. However, measurement of the enzyme can be considered if an infant develops severe clinical symptoms of unknown etiology (particularly neurologic symptoms) (CIII).
- Virologic tests are required to diagnose HIV infection in infants aged <18 months (see [Diagnosis of HIV Infection in Infants and Children](#)) (All).
- 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 regimen, unless there is adequate test information to presumptively exclude HIV infection (see the [Pediatric Opportunistic Infections Guidelines](#)) (All).
- Health care providers should routinely inquire about breastfeeding and premastication and advise caregivers on safe feeding options (All).

**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 7, 2018; last reviewed December 7, 2018)

### Panel's Recommendation

- 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