

Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States



Developed by the HHS Panel on Treatment of
HIV During Pregnancy and Prevention of Perinatal Transmission—
A Working Group of the NIH Office of AIDS Research Advisory Council (OARAC)

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It is emphasized that concepts relevant to HIV management evolve rapidly. The Panels have a mechanism to update recommendations on a regular basis, and the most recent information is available on the Clinicalinfo website (<https://clinicalinfo.hiv.gov/>).

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Maternal HIV Testing and Identification of Perinatal HIV Exposure

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Panel's Recommendations

- HIV testing is recommended as a standard of care for all sexually active people and should be a routine component of prepregnancy care **(AII)**.
- All pregnant people should be tested as early as possible during each pregnancy (see [Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations](#) and [2018 Quick Reference Guide: Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens](#) from the Centers for Disease Control and Prevention [CDC]) **(AII)**.
- Partners of all pregnant people should be referred for HIV testing when their status is unknown **(AIII)**.
- Repeat HIV testing in the third trimester is recommended for pregnant people with negative initial HIV 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 or territories that require third-trimester testing **(AII)**.
- Repeat HIV testing is recommended for pregnant people with a sexually transmitted infection or with signs and symptoms of acute HIV infection, or ongoing exposure to HIV **(AIII)**. Referral for initiation of pre-exposure prophylaxis is recommended if HIV testing is negative **(AIII)**. See [Pre-Exposure Prophylaxis \(PrEP\) to Prevent HIV During Periconception, Antepartum, and Postpartum Periods](#) for more information.
- Expedited^a HIV testing should be performed during labor or delivery for people 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 intravenous zidovudine prophylaxis should be initiated immediately **(AI)**; see [Intrapartum Care for People With HIV](#).
- When a pregnant person has a positive HIV test result during labor and delivery or postpartum, or when a newborn's expedited antibody test is positive, supplemental HIV testing should be performed on the mother (an HIV-1/HIV-2 antibody differentiation assay and in most cases an HIV RNA assay) and the infant (HIV RNA assay) **(AII)**; see [Diagnosis of HIV Infection in Infants and Children](#) for additional information.
- In these situations, an ARV regimen that is appropriate for infants who are at high risk of perinatal HIV transmission should be initiated immediately **(AI)**. See [Antiretroviral Management of Newborns With Perinatal HIV Exposure or HIV Infection](#) for guidance.
- For persons who were planning to breastfeed, breastmilk should be expressed and stored appropriately until all supplemental HIV tests are reviewed and negative **(AI)**.
- Pregnant people who were not tested for HIV before or during labor should undergo expedited HIV testing during the immediate postpartum period (or their newborns should undergo expedited HIV antibody testing) **(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 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 Infection in Infants and Children](#)).

^aThe term "expedited" is used to designate HIV testing performed in situations when a very short turnaround time is optimal. Expedited testing is dependent on the available HIV tests in each facility and may include antigen/antibody immunoassays, antibody-only assays, or HIV nucleic acid tests; see Approved HIV Tests in the text below.

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 postpubertal adolescents

Prepregnancy Counseling and Care for Persons of Childbearing Age With HIV

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Panel's Recommendations
<ul style="list-style-type: none">• Discuss reproductive desires and plans with all persons with HIV of childbearing potential on an ongoing basis throughout the course of their care (AIII).• Provide information about effective and appropriate contraceptive methods to people who do not currently desire pregnancy (AI). Offer all contraceptive methods or refer for contraceptive services. Individuals with HIV can use all available contraceptive methods (e.g., pill, patch ring, injection, implant); however, the presence of other medical co-morbidities and drug-drug interactions between hormonal contraceptives, antiretroviral (ARV) drugs, and other medications should be considered (see Table 3) (AII).• During prepregnancy counseling, provide information on safer sex; ask about the use of alcohol, nicotine products, and other substances. Provide or refer to evidence-based interventions for substance use disorder, including medication-assisted treatment for opiate use disorder (e.g., methadone, buprenorphine), and counsel patients on how to manage health risks (e.g., access to a syringe services program) when indicated. (AII).• Provide education and counseling about interventions to prevent perinatal HIV transmission, including antiretroviral therapy (ART). Explain that persons 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 <i>in utero</i> HIV transmission to the infant (AI). When fully suppressive ART is started before pregnancy and undetectable viral load is maintained throughout pregnancy and at delivery, there is no risk of HIV transmission to the infant.• For people with HIV who are considering or planning a pregnancy, begin to provide patient-centered, evidence-based counseling to support shared decision making about infant feeding (AIII) (see Infant Feeding for Individuals with HIV in the United States). Information and plans for infant feeding should be reviewed throughout pregnancy and again after delivery.• When selecting or evaluating an ARV regimen for persons of childbearing potential with HIV, consider a regimen's effectiveness, a person's hepatitis B status, and the possible adverse outcomes for the pregnant person and their fetus (AII). See Teratogenicity and Recommendations for Use of Antiretroviral Drugs During Pregnancy: Overview for more information. The Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission emphasizes the importance of counseling and shared decision-making regarding all ARV regimens for persons with HIV (AIII).
<p><i>Rating of Recommendations: A = Strong; B = Moderate; C = Optional</i></p> <p><i>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</i></p>

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

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Panel's Recommendations

- Centers for Disease Control and Prevention (CDC) guidance recommends health care providers should discuss PrEP with all sexually active people without HIV—including individuals who are trying to conceive, pregnant, postpartum, or breastfeeding—to prevent HIV acquisition (AII); counseling should include the benefits of PrEP to prevent HIV acquisition and perinatal transmission (AI) and potential adverse effects of PrEP during periconception, pregnancy, postpartum, and breastfeeding periods (AII). Health care providers should offer PrEP to those who desire PrEP or have specific indications for PrEP use (e.g., injection drug use).
- Tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) is currently the U.S. Food and Drug Administration (FDA)-approved PrEP option for HIV prevention with known safety and efficacy data in people with receptive vaginal exposure and with demonstrated safety in pregnancy. 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).
- Long-acting injectable cabotegravir (CAB-LA) is FDA approved for people with vaginal exposure to HIV. For people with PrEP indications in pregnancy, CAB-LA dosing, efficacy, and safety remain unknown. If a person receiving cabotegravir (CAB) PrEP becomes pregnant, the limited available safety data and long half-life of CAB should be discussed with the patient with shared decision-making, and the patient may benefit from expert consultation.
- Providers should counsel patients about the importance of daily adherence to oral TDF/FTC PrEP to prevent HIV acquisition (AI). Patients should be counseled to use additional HIV prevention strategies (e.g., condoms) for the first 20 days after initiating TDF/FTC PrEP and for 28 days after last potential vaginal exposure (BII). No available data support on-demand PrEP when HIV exposure occurs 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 CDC's [PrEP for the Prevention of HIV in the United States—2021 Update](#) 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).
- In cases when the individual has a partner with HIV and that partner is on antiretroviral therapy with sustained viral suppression, condomless sexual intercourse is associated with 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](#)).

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 When One or Both Partners Have HIV

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Panel's Recommendations
<p>For People Who Want to Conceive When One or Both Partners Have HIV</p> <ul style="list-style-type: none">• Expert consultation is recommended to tailor guidance to an individual's specific needs (AIII).• People 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 people with HIV—minimize the risk of HIV transmission to their infants (AI).• Both persons should be screened and treated for genital tract infections before attempting to conceive (AII).• When people have different HIV status, sexual intercourse without a condom allows conception without sexual HIV transmission to the person without HIV if the person with HIV is on antiretroviral therapy (ART) and has achieved sustained viral suppression (BII).• Administration of antiretroviral pre-exposure prophylaxis (PrEP) to the partner without HIV reduces the risk of sexual acquisition of HIV (AI) (see PrEP to Prevent HIV During Periconception, Antepartum, and Postpartum Periods):<ul style="list-style-type: none">○ 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).○ PrEP for the person without HIV is an option that reduces the risk of sexual acquisition of HIV when the partner with HIV has not achieved sustained viral suppression, their HIV viral suppression status is unknown, and/or concerns are present that the person with HIV might be inconsistently adherent to ART during the periconception period. In these situations, additional guidance for safer conception may be required if the person without HIV declines PrEP.
<p><i>Rating of Recommendations: A = Strong; B = Moderate; C = Optional</i></p> <p><i>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</i></p>

Antepartum Care for Individuals With HIV

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Panel's Recommendations
<ul style="list-style-type: none">• In addition to the standard antepartum assessments for all pregnant people, the initial evaluation of people with HIV should include an assessment of HIV disease status and recommendations for HIV-related medical care (AI). See Initial Evaluation and Continued Monitoring of HIV-Related Assessments During Pregnancy and Table 4 for the recommended schedule of HIV-related laboratory tests during pregnancy.• Amniocentesis, if clinically indicated, may be performed on pregnant people with HIV after thorough patient-centered counseling about the risks, benefits, and alternatives. The pregnant person should be receiving an effective antiretroviral (ARV) regimen and, ideally, have HIV RNA levels that are undetectable (BIII). If a pregnant person with detectable HIV RNA levels requires amniocentesis, consultation with an expert in the management of HIV during pregnancy should be considered (BIII). Data are inadequate to guide decision-making about other invasive diagnostic or therapeutic procedures; an individualized process of shared decision-making is recommended.• People with HIV should be counseled on the known benefits and potential risks of all medications, including ARV drugs used during pregnancy and postpartum. Counseling about the importance of adherence should be addressed at each visit (AIII).• Coordination of services among prenatal care providers, primary care, 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 care and enables adherence to antiretroviral therapy (AII).• During pregnancy, providers should initiate counseling about key intrapartum and postpartum considerations, including mode of delivery, lifelong HIV therapy, family planning and contraceptive options, infant feeding, infant ARV prophylaxis, and timing of infant diagnostic testing (AIII).
<p><i>Rating of Recommendations: A = Strong; B = Moderate; C = Optional</i></p> <p><i>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</i></p>

Initial Evaluation and Continued Monitoring of HIV-Related Assessments During Pregnancy

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Panel's Recommendations

- The plasma HIV RNA levels of pregnant people with HIV should be monitored at the initial antenatal visit **with a review of prior HIV RNA levels (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 36 weeks gestation, or within 4 weeks of delivery**, to inform decisions about mode of delivery (see [Intrapartum Care for People 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 **with review of prior CD4 counts (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). Patients who have been on ART for <2 years, patients with CD4 counts <300 cells/mm³, and patients 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 **reviewed in conjunction with antiretroviral (ARV) history (if prior results are available) and performed** during pregnancy in those whose HIV RNA levels are above the threshold for resistance testing (usually >500 copies/mL to 1,000 copies/mL but may be possible for HIV RNA >200 to ≤ 500 copies in some laboratories). Testing should be conducted before—
 - Initiating ART in ARV-naive pregnant people who have not been previously tested for ARV drug resistance **(AII)**;
 - Initiating ART in ARV-experienced pregnant people (including those who have received pre-exposure prophylaxis) **(AIII)**; *or*
 - Modifying ARV regimens for people with HIV who become pregnant while receiving ARV drugs or people who have suboptimal virologic response to ARV drugs that were started during pregnancy **(AII)**. See [Antiretroviral Drug Resistance and Drug Resistance Testing in Pregnancy](#).
- ART should be initiated in pregnant patients prior to receiving the results of ARV-resistance tests. ART should be modified, if necessary, based on the results of resistance testing **(AII)**.
- Laboratory testing to monitor complications of ARV drugs during pregnancy should be based on what is known about the adverse effects of the drugs an individual is receiving **(AIII)**.
- Pregnant people with HIV who are taking ART during pregnancy should undergo standard glucose screening **(AIII)**. Some experts suggest performing glucose screening early in pregnancy for those who **may be at high risk for gestational diabetes on protease inhibitor-based ART (BIII)**. For more information on ART, see [Antiretroviral Drug Regimens and Maternal and Neonatal Outcomes](#).

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

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Panel's Recommendations
<ul style="list-style-type: none"> • HIV drug-resistance testing (genotypic and, if indicated, phenotypic) should be performed in persons with HIV whose HIV RNA levels are above the threshold for resistance testing (i.e., >200 to 1,000 copies/mL). For people with confirmed HIV RNA levels >200 copies/mL but <1,000 copies/mL, drug-resistance testing may be unsuccessful but should still be considered. Perform resistance testing before— <ul style="list-style-type: none"> ○ Initiating antiretroviral therapy (ART) in antiretroviral (ARV)-naive pregnant persons who have not been previously tested for ARV resistance (AII), ○ Initiating ART in ARV-experienced pregnant persons (including those who have received pre-exposure prophylaxis) (AIII), or ○ Modifying ARV regimens for those 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 persons before receiving results of ARV-resistance testing; ART should be modified, if necessary, based on the results of resistance assays (AII). • 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 (AIII). INSTI resistance may be a concern if— <ul style="list-style-type: none"> ○ A patient received prior treatment or pre-exposure prophylaxis (PrEP) that included an INSTI, or ○ A patient has had a sexual partner on INSTI therapy who was not virologically suppressed or with unknown viral load. • Documented zidovudine (ZDV) resistance does not affect the indications for use of intrapartum intravenous ZDV (see Intrapartum Care for People With HIV) (BIII). • Choice of ARV regimen for an infant born to a person 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) (BIII). • Pregnant persons 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 individuals should be counseled about the importance of adherence to prescribed ARV medications to reduce the risk of developing resistance (AII).
<p>Rating of Recommendations: A = Strong; B = Moderate; C = Optional</p> <p>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</p>

Recommendations for the Use of Antiretroviral Drugs During Pregnancy: Overview

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Panel's Recommendations
<ul style="list-style-type: none">• All pregnant people with HIV should initiate antiretroviral therapy (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).• In addition to benefiting an individual's health and preventing HIV transmission to sexual partners, the goal of antiretroviral therapy (ART) during pregnancy is to achieve and maintain HIV viral suppression to undetectable levels (HIV RNA <50 copies/mL) to reduce the risk of perinatal transmission (AI).• Pregnant people are often excluded from clinical trials of antiretroviral (ARV) drugs, resulting in limited data regarding pharmacokinetics (PKs), drug safety, and efficacy of new ARVs in pregnancy and lactation. However, pregnancy, lactation, and the potential for pregnancy should not preclude the use of drug regimens that would be chosen for people who are not pregnant, unless adequate drug levels are not likely to be attained in pregnancy or known adverse effects outweigh potential benefits (AIII).• The selection of which ARV drugs to use during pregnancy is best made through shared decision-making between the healthcare provider and patient after discussion of the known and potential risks and benefits to the patient and fetus, acknowledging limited data (AIII). See Appendix C: Antiretroviral Counseling Guide for Health Care Providers, Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy for People Who Are Antiretroviral-Naive, and Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs.• The Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission (the Panel) uses a variety of data sources to assign ARV drugs to one of five categories for use in pregnancy: <i>Preferred</i>, <i>Alternative</i>, <i>Insufficient Data to Recommend</i>, <i>Not Recommended Except in Special Circumstances</i>, and <i>Not Recommended</i>, as outlined in Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy for People Who Are Antiretroviral-Naive and Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs for a variety of clinical scenarios.• When selecting ARV drugs for use in pregnancy or for people who are trying to conceive, the Panel recommends use of ARV drugs in the <i>Preferred</i> or <i>Alternative</i> categories whenever possible (AIII) but also tailors its recommendations to a variety of clinical scenarios; see Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs.• When choosing ARV drug regimen and weighing the benefits and risks of specific ARVs for use during pregnancy or in people who are trying to conceive, providers and pregnant people should consider multiple factors, including adverse effects, drug interactions, PKs, convenience of the individual drugs and drug combinations in the regimen, available pregnancy safety and outcome data, virologic efficacy in nonpregnant adults (and pregnant individuals if available), and the individual's resistance test results and comorbidities (AIII).• The same regimens that are recommended for the treatment of nonpregnant adults should be used in pregnant people when sufficient data suggest that appropriate drug exposure is achieved during pregnancy (AI).• In most cases, people with HIV who are receiving ART and present for pregnancy care should continue their current ART, 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 the lower limits of detection of the assay) **(AII)** (see [People with HIV Who Are Taking Antiretroviral Therapy When They Become Pregnant](#)).

- Important changes in physiology and volume of distribution during pregnancy may impact drug concentrations and effectiveness in suppressing HIV viral replication, especially later in pregnancy when viral rebound may increase transmission risk and impact the need for intrapartum zidovudine or cesarean delivery (See Table 9 in [Intrapartum Care for People with HIV](#)). Pregnant people and clinicians should review these potential impacts as early in pregnancy as possible when choosing to start, modify, or continue an ARV regimen **(AIII)** (see [People with HIV Who Are Taking Antiretroviral Therapy When They Become Pregnant](#))
- The Panel strongly recommends against discontinuing ART during pregnancy **(AII)**.
 - If an ARV drug regimen must be stopped during pregnancy, all ARV drugs should be stopped simultaneously, and a complete, effective ARV regimen should be reinitiated as soon as possible **(AII)**.
- Throughout the prepregnancy, pregnancy, and postpartum periods, clinicians should discuss current and future reproductive desires and contraceptive options, as well as the risks and benefits of conceiving or conceiving again on the current ARV regimen **(AIII)**. See [Pregnancy Counseling and Care for Persons of Childbearing Age With HIV](#) and [Postpartum Follow-Up of People With HIV](#) 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

Use of Antiretroviral Drugs to Prevent Perinatal HIV Transmission and Improve Maternal Health

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Panel's Recommendations
<ul style="list-style-type: none">• All pregnant people with HIV should initiate antiretroviral therapy (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).• Persons with HIV initiating ART should receive the support necessary to achieve viral suppression to undetectable levels as rapidly as possible and maintain an HIV viral load that is below the limit of detection prior to conception, during pregnancy, postpartum, and throughout their lives (AII). (See Recommendations for Use of Antiretroviral Drugs During Pregnancy: Overview.)• Neonates should receive antiretroviral prophylaxis or presumptive HIV therapy appropriate to their risk of perinatal HIV acquisition (AI). (See Antiretroviral Management of Newborns With Perinatal HIV Exposure or HIV Infection.)
<p>Rating of Recommendations: A = Strong; B = Moderate; C = Optional</p> <p>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</p>

Antiretroviral Therapy for People With HIV Who Are Trying to Conceive

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Panel's Recommendations

- Reproductive intentions should be reviewed at each health care encounter. The time before a planned attempt to conceive is an important opportunity to review current and alternative antiretroviral (ARV) regimens and underscore the goal of reaching viral suppression (undetectable HIV RNA) before and throughout pregnancy, along with many other aspects of preconception planning (see [Prepregnancy Counseling and Care for Persons of Childbearing Age With HIV](#)) (AIII).
- Use of contraception, regardless of type, should not be required to initiate or continue ARV regimens that would otherwise be recommended for an individual patient, even if there are limited data in pregnancy (e.g., cabotegravir/rilpivirine or bictegravir/tenofovir alafenamide/emtricitabine) (AIII). Clinicians should engage in shared decision-making, counsel on the potential benefits and risks, and be aware of the potential for reproductive coercion (AIII).
- Whenever possible, regimen initiation or changes should be made with sufficient time to achieve viral suppression before attempting to conceive or becoming pregnant (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)

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Panel's Recommendations
<ul style="list-style-type: none">• For pregnant people who have never received antiretroviral therapy (ART), ART should be initiated as soon as possible, even before results of drug-resistance testing are available, as viral suppression earlier in pregnancy has been associated with lower risk of transmission (AI). When ART is initiated before the results of the drug-resistance assays are available, the antiretroviral (ARV) regimen should be modified, if necessary, based on the resistance assay results (AII).• ARV regimens that are <i>Preferred</i> for the treatment of pregnant people with HIV who are ARV-naive include a dual-nucleoside reverse transcriptase inhibitor combination (abacavir plus lamivudine [3TC], tenofovir disoproxil fumarate plus either emtricitabine [FTC] or 3TC, or tenofovir alafenamide plus either FTC or 3TC) and either a ritonavir-boosted protease inhibitor (darunavir/ritonavir) or an integrase strand transfer inhibitor (dolutegravir) (see Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy for People Who Are Antiretroviral-Naive) (AIII).• Choice of ART regimen should be based on results of resistance testing, concurrent medical conditions, and current recommendations for ART in pregnancy (AII). For additional information, see Recommendations for Use of Antiretroviral Drugs During Pregnancy: Overview.
<p><i>Rating of Recommendations:</i> A = Strong; B = Moderate; C = Optional</p> <p><i>Rating of Evidence:</i> 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</p>

People With HIV Who Are Taking Antiretroviral Therapy When They Become Pregnant

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Panel's Recommendations

- In most cases, people 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 on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission recommends patient counseling to support informed decision-making (AIII). See [Appendix C: Antiretroviral Counseling Guide for Health Care Providers](#).
- For pregnant people on ART, antiretroviral (ARV) drug-resistance testing should be performed prior to changing an ARV regimen if HIV RNA is above the threshold for standard genotypic drug resistance testing (AI) (usually >500 copies/mL to 1,000 copies/mL) (AIII), but may be possible for HIV RNA >200 to <500 copies/mL in some laboratories (CIII). See [Antiretroviral Drug Resistance and Resistance Testing in Pregnancy](#).
- Clinicians need to consider whether pharmacokinetic changes in pregnancy, especially in the second and third trimester, may lead to a lower plasma level of some ARV drugs and necessitate increased doses, more frequent dosing, boosting, more frequent viral load monitoring, or a change in the ARV regimen (AII). See [Appendix B: Supplement: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy](#).
- Although there are no data on the use of two-drug oral regimens during pregnancy (e.g., dolutegravir [DTG] plus lamivudine [3TC], DTG plus rilpivirine [RPV]), the component drugs are recommended as Preferred or Alternative for use in pregnancy. Pregnant persons who present to care on DTG/3TC or DTG/RPV and have successfully maintained viral suppression can continue the two-drug regimen (BIII) with more frequent viral load monitoring every 1 to 2 months throughout pregnancy (CIII).
- Data about the use of long-acting injectable cabotegravir (CAB-LA) and RPV during pregnancy are extremely limited and insufficient to make a recommendation for or against use in pregnancy. Pregnant people who present to care on this regimen should be counseled about limited data. Clinicians and pregnant people should reach a shared decision about continuing this regimen with frequent viral load monitoring or switching to one of the Preferred or Alternative three-drug ARV regimens (CIII).
- The use of cobicistat-containing 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. When pregnant people present to care on one of these regimens, clinicians and pregnant people should reach a shared decision about whether to continue the regimen with frequent viral load monitoring or to switch to a different regimen that is recommended for use during pregnancy (BIII) (see [Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy for People Who Are Antiretroviral-Naive](#) and [Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs](#)). If one of these regimens is continued, absorption should be optimized by taking the drugs with food and following instructions for administration (e.g., spacing administration of vitamins containing iron and calcium) (AII). Viral load should be monitored more frequently (i.e., every 1–2 months) (CIII).
- People 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 ARV drugs that are

recommended for use during pregnancy (AIII). See [Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs](#) for more information.

- If an ARV regimen is altered during pregnancy, drugs in the new regimen should include ARV drugs that are recommended for use in pregnancy (BIII) (see [Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy for People Who Are Antiretroviral-Naive](#) and [Table 7. Situation-Specific Recommendations for Use of ARVs](#)), and more frequent virologic monitoring is warranted until viral suppression is stably observed (CIII).

Please see [Intrapartum Care for People with HIV](#) for guidance about use of intrapartum intravenous zidovudine prophylaxis and scheduled cesarean delivery for pregnant people who have not achieved viral suppression on antiretroviral therapy at delivery.

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 Previously Received Antiretroviral Medications but Are Not Currently on Antiretroviral Medications

Updated: January 31, 2023

Reviewed: January 31, 2023

Panel's Recommendations
<ul style="list-style-type: none">In choosing an antiretroviral therapy regimen for pregnant people who have previously received antiretroviral (ARV) drugs, clinicians should obtain an accurate history of all prior ARVs medications used for HIV treatment or prevention of HIV transmission, including virologic efficacy, tolerance of the medications, results of prior resistance testing, and barriers to adherence (AIII).
<p><i>Rating of Recommendations: A = Strong; B = Moderate; C = Optional</i></p> <p><i>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</i></p>

Pregnant People Who Have Not Achieved Viral Suppression on Antiretroviral Therapy

Updated: January 31, 2023

Reviewed: January 31, 2023

Panel's Recommendations
<ul style="list-style-type: none">• Regular viral load monitoring is needed in pregnancy to quickly detect lack of viral suppression (AII).• When lack of suppression is identified, a thoughtful evaluation of potential contributing factors is needed, including barriers to adherence, drug resistance, pharmacokinetic (PK) changes in pregnancy leading to insufficient drug levels, and combinations of these factors. Management of lack of viral suppression should address each of these factors if relevant (AII).• If changes to a current antiretroviral therapy (ART) regimen are needed, data are insufficient to recommend for or against adding an integrase strand transfer inhibitor to a current nonsuppressive regimen (AIII).• To detect problems with viral suppression early, more frequent viral load monitoring (every 1–2 months) is recommended when individuals are receiving regimens associated with lower drug levels in the third trimester or drugs with limited or no PK data about use in pregnancy (AII).• Consider consulting with an HIV treatment specialist when modifying ART due to inadequate viral suppression (BIII). <p>Please see Intrapartum Care for People With HIV for guidance about use of intrapartum intravenous zidovudine prophylaxis and scheduled cesarean delivery for pregnant people who have not achieved viral suppression on ART.</p>
<p>Rating of Recommendations: A = Strong; B = Moderate; C = Optional</p> <p>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</p>

Teratogenicity

Updated: January 31, 2023

Reviewed: January 31, 2023

Panel's Recommendations
<ul style="list-style-type: none">• 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, people can be counseled that ARV drugs during pregnancy generally do not increase the risk of birth defects (BIII). Providers should be aware that data on the risks of birth defects for many ARV drugs are limited and evolving (see Appendix B: Supplement: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy).• All pregnant people with HIV should initiate antiretroviral therapy (ART) as early in pregnancy as possible (AI). Pregnant people with HIV should not delay initiating ART due to concerns about teratogenicity with first trimester exposure (AIII).<ul style="list-style-type: none">• The Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission 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.• 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 pregnancies (AIII). See Introduction to the Selection of Antiretroviral Drugs In Pregnancy, People with HIV Who are Trying to Conceive, and Table 7.
<p><i>Rating of Recommendations: A = Strong; B = Moderate; C = Optional</i></p> <p><i>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</i></p>

Antiretroviral Drug Resistance and Resistance Testing in Pregnancy

Updated: January 31, 2023

Reviewed: January 31, 2023

Panel's Recommendations
<ul style="list-style-type: none">• HIV drug-resistance testing (genotypic and, if indicated, phenotypic) should be performed in persons with HIV whose HIV RNA levels are above the threshold for resistance testing (i.e., >200 to 1,000 copies/mL). For people with confirmed HIV RNA levels >200 copies/mL but <1,000 copies/mL, drug-resistance testing may be unsuccessful but should still be considered. Perform resistance testing before—<ul style="list-style-type: none">○ Initiating antiretroviral therapy (ART) in antiretroviral (ARV)-naive pregnant persons who have not been previously tested for ARV resistance (AII),○ Initiating ART in ARV-experienced pregnant persons (including those who have received pre-exposure prophylaxis) (AIII), or○ Modifying ARV regimens for those 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 persons before receiving results of ARV-resistance testing; ART should be modified, if necessary, based on the results of resistance assays (AII).• 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 (AIII). INSTI resistance may be a concern if—<ul style="list-style-type: none">○ A patient received prior treatment or pre-exposure prophylaxis (PrEP) that included an INSTI, or○ A patient has had a sexual partner on INSTI therapy who was not virologically suppressed or with unknown viral load.• Documented zidovudine (ZDV) resistance does not affect the indications for use of intrapartum intravenous ZDV (see Intrapartum Care for People With HIV) (BIII).• Choice of ARV regimen for an infant born to a person 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) (BIII).• Pregnant persons 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 individuals should be counseled about the importance of adherence to prescribed ARV medications to reduce the risk of developing resistance (AII).
<p>Rating of Recommendations: A = Strong; B = Moderate; C = Optional</p> <p>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</p>

Special Populations: Hepatitis B Virus/HIV Coinfection

Updated: January 31, 2023

Reviewed: January 31, 2023

Panel's Recommendations
<ul style="list-style-type: none">• All pregnant people with HIV should be screened during each pregnancy for hepatitis B virus (HBV) infection unless they are already known to have HBV/HIV coinfection or have serologic documentation of HBV immunity.• All pregnant people 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).• All pregnant people 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 immunoglobulin G [IgG] or total antibody [IgG and immunoglobulin M]), they should receive the HAV vaccine series (AIII).• After delivery, people with HBV/HIV coinfection should continue antiretroviral regimens that include drugs with anti-HBV activity: tenofovir disoproxil fumarate or tenofovir alafenamide plus lamivudine or emtricitabine (AII).• Pregnant people with HBV/HIV coinfection who are receiving antiretroviral therapy (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).• For pregnant people with HBV/HIV coinfection who discontinue medications with anti-HBV activity, frequent monitoring of liver function tests for potential exacerbation of HBV infection is recommended, with prompt reinstitution of treatment for HBV when a flare is suspected (BIII).• HBV/HIV coinfection is not an independent indication for cesarean delivery (see Intrapartum Care for People with HIV) (AIII).• Within 12 hours of birth, infants born to people with HBV should receive hepatitis B immune globulin and the first dose of the HBV vaccine series (AI).
<p><i>Rating of Recommendations: A = Strong; B = Moderate; C = Optional</i></p> <p><i>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</i></p>

Special Populations: Hepatitis C Virus/HIV Coinfection

Updated: January 31, 2023

Reviewed: January 31, 2023

Panel's Recommendations

- All pregnant people with HIV should be screened during the current pregnancy for hepatitis C virus (HCV) infection, ideally at the initial prenatal visit (AIII).
 - HCV antibody testing, with confirmatory HCV RNA polymerase chain reaction testing if the antibody test is positive, is recommended for screening (A).
 - HCV screening could be repeated later in pregnancy in persons 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).
- For people who are known to be HCV antibody–positive, HCV RNA and liver function tests should be checked at initiation of prenatal care to assess risk of HCV perinatal transmission and severity of liver disease (AIII).
- Pregnant people, including those with HIV/HCV coinfection, should be tested for hepatitis B surface antigen during each pregnancy, preferably in the first trimester, even if vaccinated or tested previously. If they are negative and lack evidence of immunity, they should receive the hepatitis B virus vaccine series (see [Hepatitis B Virus/HIV Coinfection](#)) (AIII).
- Pregnant people 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 immunoglobulin G [IgG] or total antibody [IgG and immunoglobulin M]), they should receive the HAV vaccine series (AIII).
- 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 agents in persons who are pregnant. If considering initiating HCV treatment in a pregnant person with HCV/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 pregnant people with HIV, including those who have HCV coinfection (AIII).
- Pregnant people 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).
- HCV treatment with direct-acting antiviral agents should be recommended and offered for people with HCV postpartum (A).
- In people with HCV infection, 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).
- HCV/HIV coinfection is not an independent indication for cesarean delivery (see [Intrapartum Care for People with HIV](#)) (AIII).
- Infants born to people 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

Updated: January 31, 2023

Reviewed: January 31, 2023

Panel's Recommendations
<ul style="list-style-type: none">• HIV-2 infection should be considered in pregnant people 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 people with HIV-2 infection should be treated based on the 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 people with HIV-2 infection (AIII).• Dolutegravir, raltegravir, or darunavir/ritonavir plus a dual-NRTI backbone of abacavir plus lamivudine (3TC), or tenofovir disoproxil fumarate or tenofovir alafenamide plus emtricitabine or 3TC are recommended for treating HIV-2 mono-infection in pregnant people and in people who are trying to conceive (AIII). Zidovudine (ZDV) plus 3TC can be used as an alternative dual-NRTI backbone. See Recommendations for Use of Antiretroviral Drugs During Pregnancy and Appendix C: Antiretroviral Counseling Guide for Health Care Providers.• If a pregnant individual is already receiving antiretroviral therapy with drugs that are active against HIV-2, treatment should be continued (AIII).• 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 people with HIV-2 infection (without HIV-1 infection) should receive a 4-week ZDV prophylactic regimen (BIII) (see Table 10. Neonatal Antiretroviral Management According to Risk of HIV Infection in the Newborn and Table 11. Antiretroviral Drug Dosing Recommendations for Newborns).• People with HIV-2 infection should receive patient-centered, evidence-based counseling to support shared decision-making about infant feeding options prior to and during pregnancy; counseling and plans for infant feeding should be reviewed again after delivery (AIII) (see Infant Feeding for Individuals with HIV in the United States).
<p>Rating of Recommendations: A = Strong; B = Moderate; C = Optional</p> <p>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</p>

Prenatal Care, Antiretroviral Therapy, and HIV Management in People with Perinatal-Acquired HIV Infection

Updated: December 30, 2021

Reviewed: December 30, 2021

Panel's Recommendations
<ul style="list-style-type: none">• The management of prenatal care and general principles of antiretroviral therapy (ART) and HIV management do not differ between pregnant people with perinatally-acquired HIV (PHIV) and those with non-perinatally acquired HIV (AII).• Using the same guiding principles that are used for heavily ART-experienced adults, optimal ARV 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 people with PHIV warrant enhanced focus on adherence interventions during pregnancy and after delivery (AII).
<p>Rating of Recommendations: A = Strong; B = Moderate; C = Optional</p> <p>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</p>

Perinatal HIV Prevention for Transgender and Gender-Diverse People Assigned Female at Birth

Updated: January 31, 2023

Reviewed: January 31, 2023

Panel's Recommendations

- The Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission has determined that, in most cases, it is appropriate to extrapolate its recommendations based on data in cisgender women to all people assigned female sex at birth, including transgender and gender-diverse people, with modification when indicated (e.g., drug interactions with gender-affirming hormones) (AIII).
- Patient-centered HIV and perinatal services should be provided using gender-affirming and shared decision-making approaches and models of care that address the unique and varied needs of transgender and gender-diverse people and reduce barriers to ongoing engagement in care that can affect adherence to antiretroviral therapy and the likelihood of viral suppression during prepregnancy, antepartum, and postpartum periods (AII).
 - Patients should be asked about their gender identity, including the pronouns they use and their language preferences, how they want to be referred to as a parent (e.g., the baby's mother, father, or by another name), and terms they prefer to use for sexual and reproductive anatomy and examinations (e.g., breast exams, pelvic exams) (AIII).
- Health care providers should assess reproductive and parenting intentions and support access to appropriate reproductive healthcare services for transgender and gender-diverse people (AIII).
- Prepregnancy care for transgender and gender-diverse people should incorporate shared decision-making that addresses needs related to gender identity, with consideration of the potential risks and benefits of gender-affirming pharmacologic treatment in relation to pregnancy (AIII). See [Pregancy Counseling and Care for Persons of Childbearing Age With HIV](#) for more information.
- Some transgender and gender-diverse patients may experience the onset or worsening of gender dysphoria and associated symptoms—such as depression—during prepregnancy, antepartum, and postpartum periods; health care providers should regularly assess patients' comfort with their care and provide referrals for mental health or other support services as needed (AIII).

For additional information, see [Transgender People With HIV](#) in the [Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With 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

Early (Acute and Recent) HIV Infection

Updated: January 31, 2023

Reviewed: January 31, 2023

Panel's Recommendations

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

- The Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission emphasizes the importance of counseling and informed decision-making regarding all antiretroviral (ARV) regimens for people with HIV **(AIII)**.
- Providers should inform individuals starting ART of the importance of strict adherence to rapidly achieve and maintain viral suppression **(AIII)**.
- Infants born to people who received a diagnosis of **early** HIV infection during pregnancy or breastfeeding are at high risk of acquiring HIV infection and should receive an ARV regimen that is appropriate for this elevated risk (see Table 10. Neonatal Antiretroviral Management According to Risk of HIV Infection in the Newborn in [Antiretroviral Management of Newborns With Perinatal HIV Exposure or HIV Infection](#)) **(AII)**. Consulting a pediatric HIV specialist regarding appropriate infant management is strongly recommended.

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

*Rating of Evidence: I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints;
II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes;
III = Expert opinion*

^a Early HIV infection represents either acute or recent HIV infection.

Intrapartum Care for People With HIV

Updated: January 31, 2023

Reviewed: January 31, 2023

Panel's Recommendations

HIV Testing for Pregnant People with Unknown HIV Status in Labor

- Pregnant people who present in labor with unknown HIV status and people 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 or recent HIV infection is suspected or if a person has had recent HIV exposure, an HIV RNA assay also should be done at the time of expedited antigen/antibody testing (AII). See [Early \(Acute and Recent\) HIV Infection](#).

Intrapartum Antiretroviral Therapy (ART), ZDV Prophylaxis, and Mode of Delivery for Pregnant People with HIV

- See Table 9: [Intrapartum Care and Recommended Interventions to Prevent Perinatal HIV Transmission for Pregnant People with HIV Based on HIV RNA Levels at the Time of Delivery](#) below.
- Patients should continue taking their antepartum ART on schedule during labor and before scheduled cesarean delivery (AIII).
- For individuals with HIV RNA >1,000 copies/mL or unknown HIV RNA near the time of delivery (within 4 weeks of 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) known or 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 patients 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 of gestation is recommended to minimize perinatal HIV transmission, irrespective of administration of antepartum ART (AII).
 - Management of patients 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 individuals receiving ART with HIV RNA ≤1,000 copies/mL near the time of delivery (within 4 weeks of delivery)
 - IV ZDV is **not** required for people who meet **ALL** of the following three criteria: (1) are receiving ART, (2) have HIV RNA <50 copies/mL within 4 weeks of delivery, and (3) are adherent to their ARV regimen (BII).
 - IV ZDV may be considered for people with HIV RNA ≥50 copies/mL and ≤1,000 copies/mL within 4 weeks of delivery (BII). Data are insufficient to determine whether administration of IV ZDV to people 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 their recent ART adherence and preferences, and involving expert consultation if needed (CII).
 - Scheduled cesarean delivery performed solely for prevention of perinatal HIV transmission in those 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 pregnant people with HIV RNA levels $\leq 1,000$ 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 pregnant people on ART with HIV RNA $\leq 1,000$ 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 9 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)**.
- Artificial rupture of membranes and operative vaginal delivery with forceps or a vacuum extractor should follow standard obstetric indications but should be avoided if possible in those with HIV RNA ≥ 50 copies/mL **(BIII)**.
- The ARV regimen a patient is receiving should be taken into consideration when using methergine to treat excessive postpartum bleeding caused by uterine atony.
 - In patients 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 patients 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 Follow-Up of People With HIV

Updated: January 31, 2023

Reviewed: January 31, 2023

Panel's Recommendations
<ul style="list-style-type: none">• Continuous 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 individual and their HIV care provider, ideally before delivery, taking into consideration the recommended regimens for nonpregnant adults (AIII) and plans for future pregnancies.• Because the immediate postpartum period poses unique challenges to ART adherence and retention in HIV care, arrangements for new or continued supportive services should be made throughout pregnancy and before postpartum hospital discharge (AII).• People with a positive HIV test during labor should receive confirmatory testing; see Maternal HIV Testing and Identification of Perinatal HIV Exposure. If testing confirms HIV infection, ART should be offered, and the person should be given a supply of ART before postpartum hospital discharge to prevent treatment interruption (AII). Immediate linkage to HIV care and comprehensive follow-up also is needed (AII).• Infants of people who have HIV newly diagnosed in the intrapartum period should begin presumptive HIV therapy and a supply of ART for their infants should be provided before postpartum hospital discharge (AII) (see Antiretroviral Management of Newborns With Perinatal HIV Exposure or HIV Infection).• People with HIV should receive evidence-based counseling to support shared decision-making about infant feeding options prior to and during pregnancy; counseling and plans for infant feeding should be reviewed again after delivery (AIII) (see Infant Feeding for Individuals With HIV in the United States).• Clinicians should discuss future reproductive plans and timing, as well as the risks and benefits of conceiving while on specific antiretroviral (ARV) medications and the use of appropriate contraceptive options to prevent unintended pregnancy and counsel patients about optimal interpregnancy intervals (AII) (see Pregnancy Counseling and Care for Persons of Childbearing Age With HIV).• Contraceptive counseling should involve shared decision-making and should start during the prenatal period; a contraceptive plan should be developed before postpartum hospital discharge, as desired by the patient (AII).
<p>Rating of Recommendations: A = Strong; B = Moderate; C = Optional</p> <p>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</p>

Infant Feeding for Individuals With HIV in the United States

Updated: January 31, 2023

Reviewed: January 31, 2023

Panel's Recommendations

- People with HIV should receive evidence-based, patient-centered counseling to support shared decision-making about infant feeding. Counseling about infant feeding should begin prior to conception or as early as possible in pregnancy; information about and plans for infant feeding should be reviewed throughout pregnancy and again after delivery (AIII). During counseling, people should be informed that—
 - Replacement feeding with properly prepared formula or pasteurized donor human milk from a milk bank eliminates the risk of postnatal HIV transmission to the infant (AI).
 - Achieving and maintaining viral suppression through antiretroviral therapy (ART) during pregnancy and postpartum decreases breastfeeding transmission risk to less than 1%, but not zero (AI).
- Replacement feeding with formula or banked pasteurized donor human milk is recommended to eliminate the risk of HIV transmission through breastfeeding when people with HIV are not on ART and/or do not have a suppressed viral load during pregnancy (at a minimum throughout the third trimester), as well as at delivery (AI).
- Individuals with HIV who are on ART with a sustained undetectable viral load and who choose to breastfeed should be supported in this decision (AIII).
- Individuals with HIV who choose to formula feed should be supported in this decision. Providers should ask about potential barriers to formula feeding and explore ways to address them (AIII).
- Engaging Child Protective Services or similar agencies is not an appropriate response to the infant feeding choices of an individual with HIV (AIII).
- Clinicians are encouraged to consult the national [Perinatal HIV/AIDS](#) hotline (1-888-448-8765) with questions about infant feeding by individuals with HIV (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

Antiretroviral Management of Newborns With Perinatal HIV Exposure or HIV Infection

Updated: January 31, 2023

Reviewed: January 31, 2023

Panel's Recommendations
<ul style="list-style-type: none">• 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 (AI).• 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 the following:<ul style="list-style-type: none">○ 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.○ 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).• For newborns at low-risk of perinatal HIV acquisition, a 2-week zidovudine (ZDV) ARV regimen is recommended for ARV prophylaxis if the newborn is ≥ 37 weeks gestation and is born to a person with HIV who—<ul style="list-style-type: none">○ Is currently receiving and has received at least 10 consecutive weeks of ART during pregnancy (BII); and○ Has achieved and maintained or maintained viral suppression (defined as at least two consecutive tests with HIV RNA < 50 copies/mL obtained at least 4 weeks apart) for the duration of pregnancy (AII); and○ Has a viral load < 50 copies/mL at or after 36 weeks (AII); and○ Did not have acute HIV infection during pregnancy (BII); and○ Has reported good ART adherence, and adherence concerns have not been identified (BII).• Infants born to individuals who do not meet the criteria above but who have a viral load < 50 copies/mL at or after 36 weeks gestation should receive ZDV for 4 to 6 weeks (BII).• Newborns at high risk of perinatal acquisition of HIV should receive presumptive HIV therapy with 3-drug regimens administered from birth for 2 to 6 weeks (see Tables 10 and 11); if the duration of the 3-drug regimen is shorter than 6 weeks, ZDV should be continued alone, to complete total of 6 weeks of prophylaxis. Newborns at high risk of HIV acquisition include those born to people with HIV who—<ul style="list-style-type: none">○ Have not received antepartum 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 **at least two consecutive tests with HIV RNA level <50 copies/mL obtained at least 4 weeks apart**) within 4 weeks of delivery **(AIII)**, or
- Have primary or acute HIV infection during pregnancy **(AI)**.
- All premature infants <37 weeks gestation who are not at high risk of perinatal acquisition of HIV should receive ZDV for 4 to 6 weeks **(BII)**.
- Infants of people who have primary or acute HIV infection while breastfeeding should be managed like infants at high risk of perinatal transmission with presumptive HIV therapy (see [Table 10](#)) **(AII)**.
- 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)**.
- If an individual 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)** (see [What to Start](#) in the [Pediatric Antiretroviral Guidelines](#)).
- People with HIV should receive patient-centered, evidence-based counseling to support shared decision-making about infant feeding. See [Infant Feeding for Individuals With HIV in the United States](#).
- Providers with questions about ARV management of perinatal HIV exposure should consult an expert in pediatric HIV infection or 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

Updated: January 31, 2023

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Panel's Recommendations

- Virologic assays (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 and HIV antigen/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 **maternal** antiretroviral therapy (ART), or by antiretroviral (ARV) drugs administered to the infant as prophylaxis or presumptive HIV therapy.
- 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 (see Table 13 below) 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 ARV drugs are discontinued **(BII)**.
- For infants with perinatal HIV exposure who are being breastfed, virologic diagnostic testing is recommended at birth, 14 to 21 days, 1 to 2 months, and 4 to 6 months of age **(AII)**. An additional virologic test should be performed between the 1-to-2-month and 4-to-6-month time points if the gap between tests is greater than 3 months. See [Infant Feeding for Individuals With HIV in the United States](#).
 - Virologic diagnostic testing should be performed every 3 months during breastfeeding **(BII)**;
 - After cessation of breastfeeding, irrespective of when breastfeeding ends, virologic diagnostic testing should be performed at 4 to 6 weeks, 3 months, and 6 months after cessation **(BII)**.
- A positive virologic test should be confirmed as soon as possible by a repeat virologic test **(AII)**.
- Definitive exclusion of HIV infection in non-breastfed infants is based on two or more negative virologic tests, with one negative test obtained at age ≥ 1 month (and at least 2 -6 weeks after discontinuation of multi-drug ARV prophylaxis/presumptive HIV therapy) and one at age ≥ 4 months, or two negative HIV antibody tests from separate specimens that were obtained at age ≥ 6 months **(AII)**.
- Additional HIV testing (e.g., HIV RNA or HIV DNA NAT, HIV antibody, HIV antigen/antibody) is not needed routinely for non-breastfed infants who meet the criteria for definitive exclusion of HIV and who have had no known or suspected HIV exposure after birth.
- Infants with potential HIV exposure after birth (e.g., from **maternal HIV diagnosis during** breastfeeding, premasticated feeding, sexual abuse, contaminated blood products, percutaneous exposure) who are aged <18

months require additional testing using HIV RNA/DNA NAT assays to establish their HIV status. Infants aged ≥ 18 months who have these potential exposures require HIV antigen/antibody testing.

- Age-appropriate HIV testing also is recommended for infants and children with signs and/or symptoms of HIV, even in the absence of documented or suspected HIV exposure.
- For children aged >24 months and for children **aged 18 to ≤ 24 months** with non-perinatal HIV exposure only, HIV antibody (or HIV antigen/antibody) tests are recommended for diagnostic testing (**AII**).
- 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- Perinatal HIV/AIDS](#) provides consultations on issues related to the management of perinatal HIV infection, including diagnostic testing (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

Updated: January 31, 2023

Reviewed: January 31, 2023

Panel's Recommendations
<ul style="list-style-type: none"> • All newborns perinatally exposed to HIV should receive appropriate antiretroviral (ARV) drugs as soon as possible, preferably within 6 hours, after delivery (see Antiretroviral Management of Newborns With Perinatal HIV Exposure or HIV Infection) (AI). • For infants in whom presumptive HIV therapy is initiated, hemoglobin and neutrophil counts should be obtained at baseline. If combination ARV drugs are continued through 4 weeks, hemoglobin and neutrophil counts should be remeasured at that time (AI). • With 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, other ARV drugs, or certain concomitant medications; and the specific ARV drugs used in the birthing parent's antepartum drug regimen. Infants who are found to have hematologic abnormalities may need to discontinue or switch ARV drugs, and consultation with an expert in pediatric HIV infection is advised. (CIII). • Nucleic acid tests (i.e. DNA and RNA PCR, RNA PCR assays) are required to diagnose HIV infection in infants aged <18 months (see Diagnosis of HIV Infection in Infants and Children) (AII). • To prevent <i>Pneumocystis jirovecii</i> pneumonia (PJP), all infants born to persons with HIV should begin PJP prophylaxis at age 4 to 6 weeks, unless adequate test information is available to presumptively exclude HIV infection (see the Pneumocystis jirovecii Pneumonia in the Pediatric Opportunistic Infections Guidelines) (AII). • Health care providers should inquire routinely about infant feeding plans and/or breastfeeding desires, as well as the use of pre-masticated (pre-chewed or pre-warmed) food. Counseling against pre-mastication and discussion of safe infant feeding options should be provided (see Infant Feeding for Individuals With HIV in the United States) (AIII).
<p>Rating of Recommendations: A = Strong; B = Moderate; C = Optional</p> <p>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</p>

Long-Term Follow-Up of Infants Exposed to Antiretroviral Drugs

Updated: January 31, 2023

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Panel's Recommendations
<ul style="list-style-type: none">• Children with perinatal exposure to HIV and antiretroviral (ARV) drugs who develop significant organ system abnormalities of unknown etiology, particularly of the nervous system or heart, should be evaluated for potential metabolic dysfunction (CIII).• It is important that the long-term medical record of a child without HIV includes information about perinatal HIV and ARV exposure (BIII).
<p><i>Rating of Recommendations: A = Strong; B = Moderate; C = Optional</i></p> <p><i>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</i></p>