

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

Panel's Recommendations

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

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

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

Women who are taking antiretroviral therapy (ART) for HIV infection should continue their ART regimen during pregnancy, provided it is well tolerated, safe, and effective in suppressing viral replication. Discontinuing or altering therapy could cause an increase in viral load, leading to disease progression, a decline in immune status, and an increased risk of perinatal HIV transmission.¹ Maintenance of viral suppression is paramount for both maternal health and the prevention of perinatal transmission. However, a change in ART may be indicated or considered in specific circumstances. The Panel emphasizes the importance of patient counseling and informed decision making when changing ARV regimens during pregnancy. For additional information, see [Appendix C: Antiretroviral Counseling Guide for Health Care Providers](#).

Women who present during pregnancy on drugs that are not recommended for use because of toxicity (e.g., stavudine, didanosine) should stop taking these drugs and switch to other antiretroviral (ARV) drugs that are recommended for use in pregnancy (see [Table 4](#) and [Table 5](#)).

No data exist on the use of two-drug regimens in pregnancy (e.g., DTG plus lamivudine, DTG plus rilpivirine [RPV]); women who present to care on one of these regimens should switch regimens or add additional ARV agents to these regimens.

The use of regimens containing atazanavir/cobicistat, darunavir/cobicistat, or elvitegravir/cobicistat (EVG/c), is associated with lower plasma drug exposures during the second and third trimesters of pregnancy due to the physiologic changes associated with pregnancy. These low drug exposures pose an increased risk of virologic failure in the second and third trimesters and potential perinatal HIV transmission. When a pregnant woman presents to care on one of these regimens, providers should consider continuing the regimen with more frequent viral load monitoring or switching to a more effective regimen that is recommended for use in pregnant women (see [Table 4](#) and [Table 5](#)).²⁻⁴ A recent multicenter, retrospective study of 134 pregnant women with HIV who received elvitegravir (EVG)-containing ART at any time during pregnancy reported that 81.3% of study participants had viral suppression at delivery (HIV RNA <40 copies/mL); among 68 women who initiated EVG before pregnancy and continued receiving EVG through delivery, the rate of viral suppression at delivery was 88.2%. The perinatal HIV transmission rate was 0.8% in this study.⁵ If one of these regimens is continued, absorption should be optimized by taking the drugs with food. Women who are taking regimens that include EVG/c should take ARV drugs and prenatal vitamins ≥ 2 hours apart. In addition, viral load should be monitored more frequently (e.g., every 1–2 months) in patients taking cobicistat-boosted regimens (see [Monitoring of the Woman and Fetus During Pregnancy](#)).³ Lack of virologic suppression on subsequent testing indicates a need for a regimen change, and a woman may need a scheduled cesarean delivery if the lack of suppression is detected late in pregnancy.

Although pharmacokinetic (PK) data indicate that RPV plasma concentration is reduced during the second and third trimesters of pregnancy, the reduction is less than the reductions seen with the cobicistat-containing regimens described above, and most women will have adequate exposure. Standard RPV dosing is recommended, and viral load should be monitored frequently (e.g., every 1–2 months; see [Recommendations for Use of Antiretroviral Drugs During Pregnancy](#)).

As newer, highly effective ARV drugs are approved by the Food and Drug Administration, women with HIV may present for prenatal care on ART regimens that include ARV drugs for which significant experience in pregnancy and limited PK and safety data are lacking. If questions arise about specific drugs in an ART regimen, providers are encouraged to consult with an HIV perinatal specialist before discontinuing or altering a fully suppressive regimen that is well tolerated. In addition, more frequent virologic monitoring is warranted when an ARV regimen is altered during pregnancy. Because little is known about the use of newly approved drugs during pregnancy, providers should make every effort to report all ART exposures in pregnant women to the [Antiretroviral Pregnancy Registry](#).

Women with HIV who are on ART and who present for care during the first trimester should be counseled regarding the benefits and potential risks of receiving ARV drugs during this period. Providers should emphasize that continuing an effective ARV regimen is recommended. Nonhuman primate data and retrospective case reports have raised concerns about an association between EFV use during the first trimester and an increased risk of neural tube defects in infants (for more details, see [Efavirenz](#)). However, a meta-analysis that included data on 2,026 women with first-trimester EFV exposure from 21 prospective studies did not find an increased relative risk (RR) of overall birth defects in infants born to women who received EFV-based regimens compared with women who received regimens that did not include EFV (RR 0.78; 95% confidence interval, 0.56–1.08).⁶ A recent multicohort analysis of seven observational studies across 13 European countries and Thailand included 24,963 live births to women with HIV. This study evaluated the incidence of birth defects among infants who had been exposed to either EFV-based ART (n = 1,200) or ART that did not contain EFV (n = 7,537) at the time of conception or during the first trimester; the study also evaluated infants who were not exposed to ART (n = 16,226) at the time of conception or during the first trimester. No difference was found in the prevalence of birth

defects among infants in these three groups.⁷ The Panel recommends continuing to use EFV in pregnant women who are receiving EFV-based ART, provided that the ARV regimen is well tolerated and results in virologic suppression.

Resistance testing should be performed when considering altering an ARV regimen in a pregnant woman who is experiencing virologic failure and who has HIV RNA levels >1,000 copies/mL. In individuals who have HIV RNA levels >500 copies/mL but <1,000 copies/mL, testing may be unsuccessful, but it still should be considered. The results can be used to select a new regimen with a greater likelihood of suppressing viral replication to undetectable levels.

During and after pregnancy, clinicians should discuss future reproductive plans and timing, risks and benefits of conceiving on specific ARV medications, and contraceptive options to prevent unintended pregnancy (see [Preconception Counseling and Care for Women of Childbearing Age with HIV](#)).

References

1. Floridia M, Ravizza M, Pinnetti C, et al. Treatment change in pregnancy is a significant risk factor for detectable HIV-1 RNA in plasma at end of pregnancy. *HIV Clin Trials*. 2010;11(6):303-311. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/21239358>.
2. Crauwels HM, Osiyemi O, Zorrilla C, et al. Reduced exposure to darunavir and cobicistat in HIV-1-infected pregnant women receiving a darunavir/cobicistat-based regimen. *HIV Med*. 2019;20(5):337-343. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/30873741>.
3. Momper J, Best BM, Wang J, et al. Elvitegravir/cobicistat pharmacokinetics in pregnant and postpartum women with HIV. *AIDS*. 2018;32(17):2507-2516. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/30134297>.
4. van der Galien R, Ter Heine R, Greupink R, et al. Pharmacokinetics of HIV-integrase inhibitors during pregnancy: mechanisms, clinical implications and knowledge gaps. *Clin Pharmacokinet*. 2018;58(3):309-323. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/29915921>.
5. Badell ML, Sheth AN, Momplaisir F, et al. A multicenter analysis of elvitegravir use during pregnancy on HIV viral suppression and perinatal outcomes. *Open Forum Infect Dis*. 2019;6(4):ofz129. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/31037241>.
6. Ford N, Mofenson L, Shubber Z, et al. Safety of efavirenz in the first trimester of pregnancy: an updated systematic review and meta-analysis. *AIDS*. 2014;28 Suppl 2:S123-131. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/24849471>.
7. Martinez de Tejada B, European Pregnancy Paediatric HIV Cohort Collaboration Study Group. Birth defects after exposure to efavirenz-based antiretroviral therapy at conception/first trimester of pregnancy: a multi-cohort analysis. *J Acquir Immune Defic Syndr*. 2019;80(3):316-324. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/30570524>.