When Antiretroviral Therapy Is Being Taken When Pregnancy Occurs

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Panel's Recommendations

- In most cases, when a patient is already taking antiretroviral therapy (ART) at the time of presentation for pregnancy care, the ART regimen should be continued 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.
- Clinicians should assess need in late pregnancy for changes in dosing, boosting, viral load monitoring, or choice of ARV (or ARVs) in current regimen based on pharmacokinetic changes, especially in the second and third trimester, which may lead to a lower plasma levels **(AII).** See Appendix B: Supplement: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy.
- Although there is very limited 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. If DTG/3TC or DTG/RPV is used during pregnancy at the time of presentation and viral suppression has been successfully maintained, the two-drug regimen can be continued **(BIII)** with viral load monitoring, but they are otherwise **not recommended** (see Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs) **(CIII).**
- Data about the use of long-acting injectable cabotegravir and RPV (LA CAB/RPV) during pregnancy are limited and insufficient to make a recommendation for or against use in pregnancy. When this regimen is used during pregnancy at the time of presentation, counseling about limited data should be provided. In conjunction with an HIV expert, a shared decision should be reached about continuing this regimen with frequent viral load monitoring (every 1–2 months) or switching to one of the Preferred or Alternative three-drug oral regimens **(CIII).** Expert opinion supports continuation of LA CAB/RPV with dosing every 4 weeks (as opposed to every 8 weeks) during pregnancy if there are barriers to oral ART adherence and if viral suppression is present at the start of pregnancy and maintained throughout pregnancy.
- The use of cobicistat (COBI)-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 one of these regimens is used during pregnancy at the time of presentation, a shared decision should be reached 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 When Antiretroviral Therapy Has Never Been Received and Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs). If a COBI-containing regimen 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).** In these instances, viral load should be monitored more frequently (i.e., every 1–2 months) **(CIII).**
- When a regimen that is not fully suppressive is used during pregnancy at presentation, adherence barriers, drug–drug and drug–food interactions, and HIV drug resistance should be carefully evaluated to determine whether a change in ART regimen is indicated. See Lack of Viral Suppression While on Antiretroviral Therapy in Pregnancy for additional guidance.

- If an ARV regimen is altered during pregnancy, 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 When Antiretroviral Therapy Has Never Been Received and Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs), and more frequent virologic monitoring is warranted until stable viral suppression is observed **(CIII).**
- ARV drug-resistance testing should be performed prior to changing an ARV regimen when HIV RNA levels >200 copies/mL (**AI** for >1,000 copies/mL, **AIII** for 501–1,000 copies/mL, **CIII** for 201–500 copies/mL). For confirmed HIV RNA levels >200 copies/mL but <500 copies/mL, drug-resistance testing may be unsuccessful but should still be considered. See Antiretroviral Drug Resistance and Resistance Testing in Pregnancy.

Please see Intrapartum HIV Care for guidance about use of intrapartum intravenous zidovudine prophylaxis and scheduled cesarean birth for instances when viral suppression on ART has not been achieved at birth.

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*

Management on Fully Suppressive Antiretroviral Therapy

In general, **when a fully suppressive antiretroviral (ARV) regimen is already being used when pregnancy occurs, the antiretroviral therapy (ART) regimen should be continued.** The Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission (the Panel) recommends that effective ART regimens should not be changed just because the regimen includes ARV drugs that are not *Preferred* or *Alternative* for use in pregnancy. Regimens that include an ARV drug with proven substantial fetal safety risk should be changed; however, no currently licensed ARV drug meets this criterion. 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] In a study from the French Perinatal cohort among 1,797 women with HIV RNA levels <50 copies/mL before 14 weeks of gestation, change in ARV regimen in 411 women due to safety concerns based on existing guidelines at the time of pregnancy did not result in loss of virologic control.[2] However, among 662 pregnancies that were followed in Italy between 2001 and 2008, treatment modification during pregnancy was independently associated with HIV RNA level >400 copies/mL in late pregnancy (adjusted odds ratio [aOR] 1.66; 95% CI, 1.07–2.57; $P = 0.024$).[1] This highlights the importance of establishing potent and well-tolerated regimens prior to pregnancy, using *Preferred* and *Alternative* ARVs for use in pregnancy whenever possible, to maximize effectiveness and minimize the need for modifying treatment in pregnancy.

Physiologic changes that occur during pregnancy may result in lower levels of certain ARVs, resulting in loss of virologic control with the potential for perinatal transmission. For patients who have achieved viral suppression and become pregnant while receiving regimens with a potential increased risk of virologic failure during pregnancy due to pharmacokinetic (PK) concerns (e.g., cobicistat [COBI]-boosted regimens, oral rilpivirine [RPV]) or regimens with insufficient data about dosing and/or safety in pregnancy (e.g., doravirine [DOR], oral two-drug regimens, long-acting injectables for HIV treatment [cabotegravir (CAB), RPV, and lenacapavir]), clinicians need to consider whether to continue the regimen or switch to a different regimen that is recommended for use during pregnancy[3-5] (see Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy When Antiretroviral Therapy Has Never Been Received and Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs During Pregnancy and When Trying to Conceive).

For regimens with PK concerns or those with insufficient data about dosing in pregnancy, a shared decision may be reached to continue the suppressive regimen with frequent viral load monitoring (every 1–2 months, understanding that switching may be needed later in pregnancy and that

potential viral rebound may increase perinatal transmission risk and lead to cesarean birth), or they may elect to switch to a recommended oral regimen as soon as pregnancy is recognized. In these cases, the Panel emphasizes the importance of patient counseling and informed decision-making, including consideration of individual factors (such as ARV resistance or intolerance, or difficulty with adherence to other regimens) that may increase the risk of virologic failure with a switch to a new regimen. When choosing to switch any ART regimen in pregnancy when virologic suppression is already achieved, clinicians should closely monitor tolerability of the new regimen, evaluate for adverse effects, and perform more frequent viral load monitoring (i.e., every 1–2 months). For additional information, see Appendix C: Antiretroviral Counseling Guide for Health Care Providers.

Cobicistat-Boosted Regimens

Clinicians and patients should be aware that the use of atazanavir/cobicistat, darunavir/cobicistat, or elvitegravir/cobicistat (EVG/c) is associated with lower plasma drug exposures (both of COBI and of the drug being boosted) 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 one of these regimens is used during pregnancy at the time of presentation, providers should consider continuing the regimen with more frequent viral load monitoring (i.e., every 1–2 months) or switching to a different regimen that is recommended for use during pregnancy (see Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy When Antiretroviral Therapy Has Never Been Received and Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs During Pregnancy and When Trying to Conceive).[3-5] A multicenter, retrospective study of 134 pregnant women with HIV who received EVG/c-containing ART at any time during pregnancy reported that 81.3% of study participants had viral suppression at birth (HIV RNA <40 copies/mL); among 68 women who initiated EVG/c before pregnancy and continued receiving EVG/c through birth, the rate of viral suppression at birth was 88.2%. The perinatal HIV transmission rate was 0.8% in this study.[6] If a COBI-containing regimen 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 if used with EVG/c).

Doravirine

Data on DOR use during pregnancy are extremely limited and insufficient to make a recommendation for or against use in pregnancy. PK data on DOR in human pregnancy are available only from PK modeling data based on *ex vivo* studies of placental transfer.[7,8] If pregnancy occurs with viral suppression while receiving regimens with DOR, counseling should be provided about limited available data; see Doravirine. A shared decision should be reached about continuing DOR with frequent viral load monitoring (i.e., every 1–2 months) or switching to one of the *Preferred* or *Alternative* regimens.

Oral Two-Drug Regimens

Currently, limited data exist on the use of oral two-drug regimens in pregnancy (e.g., dolutegravir [DTG] plus lamivudine [3TC] and DTG plus RPV). However, for both DTG/3TC and DTG/RPV, there are data in nonpregnant persons showing noninferiority when compared to a standard three-drug regimen.[9,10] The component drugs in each of the oral two-drug regimens (DTG, 3TC, RPV) have well-described PK that are adequate in pregnancy, and the individual drug components are recommended as *Preferred* or *Alternative* ARV drugs by the Panel. The combination of DTG/3TC is also now classified as an *Alternative* initial ART regimen for use in pregnancy when long-acting injectable CAB (CAB-LA) has not been used for pre-exposure prophylaxis (PrEP), HIV RNA ≤500,000 copies/mL, there is no hepatitis B virus coinfection, and HIV

genotypic resistance testing demonstrates sensitivity to 3TC (see Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy When Antiretroviral Therapy Has Never Been Received).

Although 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 COBI-containing regimens described above, and there should be adequate exposure during most pregnancies. An observational study of 188 pregnant people on oral RPV as part of a three-drug regimen at birth found that 182 (96.8%) had viral load <200 copies/mL.[11] Standard RPV dosing is recommended when used as part of a three-drug regimen, and viral load should be monitored frequently (e.g., every 1–2 months; see Rilpivirine, Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs During Pregnancy and When Trying to Conceive). If DTG/3TC or DTG/RPV is used during pregnancy at the time of presentation and viral suppression has been successfully maintained, the two-drug regimen can be continued with viral load monitoring, but they are otherwise not recommended (see Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs During Pregnancy and When Trying to Conceive).

Long-Acting Injectable Cabotegravir and Rilpivirine

Data on long-acting injectable CAB and RPV (LA CAB/RPV) are currently limited. A small number of patients without HIV who became pregnant while enrolled in the initial trials of CAB-LA for PrEP stopped the medication once pregnancy was recognized, usually in the first trimester. In these patients, the pharmacologic washout was similar in pregnant and nonpregnant adults.[12,13] A secondary analysis of HPTN 084 included 30 patients on CAB-LA for PrEP who became pregnant and found no increased risk of composite poor pregnancy outcomes; the apparent terminal phase half-life of CAB in pregnant women was not significantly different from that in nonpregnant women.[14] A case report describing bimonthly LA CAB/RPV prior to and during a single pregnancy found that CAB concentrations during pregnancy were comparable to those for nonpregnant individuals; however, RPV was 70% to 75% lower. The mother's HIV viral load remained undetectable throughout pregnancy, and the infant's HIV RNA test was negative.[15] In the HPTN 084 open-label extension PK substudy of 50 participants who took CAB-LA for PrEP before and during pregnancy, CAB-LA concentrations declined over the course of the pregnancy; however, drug levels remained above protocol-specific target levels.[16] While data in nonpregnant adults suggest slower washout (and thus potentially higher CAB levels) with intramuscular CAB among people with obesity,[17] this may not be applicable to the weight gain that is due to pregnancy, as the volume of distribution in pregnancy differs from that in obesity. Prior data have shown concern for lower concentrations of oral RPV in the third trimester,[18] as above. A PK modeling study of LA CAB/RPV in pregnancy suggested that monthly CAB-LA could maintain antiviral efficacy throughout pregnancy, but that bimonthly administration may require careful clinical evaluation. However, monthly or bimonthly long-acting injectable RPV in pregnancy may not adequately maintain certain target levels for antiviral efficacy in pregnancy.[19]

Some patients who have achieved virologic suppression on LA CAB/RPV experienced previous challenges with oral ART, such that switching back to oral ART could increase the risk of virologic rebound. A shared decision should be reached about continuing this regimen with frequent viral load monitoring (every 1–2 months) or switching to one of the *Preferred* or *Alternative* three-drug ARV regimens in conjunction with an HIV expert. In light of the limited available PK data, expert opinion supports continuation of LA CAB/RPV with dosing every 4 weeks (as opposed to every 8 weeks) during pregnancy if there are barriers to oral ART adherence and if viral suppression is present at the start of pregnancy and maintained throughout pregnancy.

When switching from LA CAB/RPV to an oral regimen in pregnancy, the timing of the switch must take into account the long half-life of the long-acting injectable formulation (median 5.6–11.5 weeks) with persistence of the drug for up to 12 months or longer.[20] When LA CAB/RPV injections are

stopped, the Panel recommends initiating an alternative fully suppressive ARV regimen no later than 1 month after the final LA CAB/RPV injection.[21] Dosing recommendations, including guidance for switching to an oral regimen, can be found in the prescribing information.[20,22] For additional information, see Optimizing Antiretroviral Therapy in the Setting of Viral Suppression and Discontinuation or Interruption of Antiretroviral Therapy in the Adult and Adolescent Antiretroviral Guidelines.

When Full Suppression With Antiretroviral Therapy Is Not Achieved When Pregnancy Occurs

People who are not fully suppressed and who are currently taking ART should be evaluated carefully for adherence barriers, drug–drug interactions, drug–food requirements, and HIV drug resistance, with every effort made to achieve rapid and full viral suppression through adherence interventions or medication changes (see Lack of Viral Suppression While on Antiretroviral Therapy in Pregnancy).

When ART is used during pregnancy, ARV drug-resistance testing should be performed prior to changing an ARV regimen if HIV RNA levels are >200 copies/mL. If there has been any prior long-acting CAB exposure (as part of ART or PrEP), the Panel recommends also performing an integrase strand transfer inhibitor genotype test. For HIV RNA levels >200 copies/mL but <500 copies/mL, drug-resistance testing may be unsuccessful but should still be considered (see Antiretroviral Drug Resistance and Resistance Testing in Pregnancy).

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