Appendix C: Antiretroviral Counseling Guide for Health Care Providers

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Decision-Making About Antiretroviral Drugs for People Who Are Pregnant or Are Trying to Conceive

This guide summarizes information, based on currently available data, to support counseling about the use of antiretroviral (ARV) drugs and antiretroviral therapy (ART) options during pregnancy for people who are pregnant or are trying to conceive. Individuals should be counseled about the benefits and potential risks of ARV drugs to promote informed, individual decision-making.

For people who are pregnant or are trying to conceive, effective ART with sustained viral suppression maximizes their health and the prevention of perinatal HIV transmission. The risk of perinatal HIV transmission is reduced to the lowest levels (1% or less) in people with HIV who initiate ART prior to conception and have sustained viral suppression to undetectable levels throughout pregnancy. See Use of Antiretroviral Drugs to Prevent Perinatal HIV Transmission and Improve Maternal Health.

Before, during, and after pregnancy, it is important to discuss future childbearing desires and plans, the potential benefits and risks of conceiving while taking specific ARV medications, and contraceptive options to prevent unintended pregnancy.

General Antiretroviral Counseling for People Who Are Pregnant or Are Trying to Conceive

- As part of shared decision-making, provide information to individuals who are pregnant or are trying to conceive to help them understand and consider the benefits, advantages, disadvantages, and potential risks associated with the use of each individual ARV drug they are currently receiving or will be initiating. These factors include dosing frequency, side effects or tolerability issues, and adverse pregnancy outcomes (e.g., preterm delivery, birth defects). For additional information, refer to 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, Teratogenicity, and Antiretroviral Drug Regimens and Maternal and Neonatal Outcomes.
- People who are trying to conceive should receive information about the use of specific ARV regimens during pregnancy to enable them to make informed decisions before they become pregnant.
- Explain that not enough is known about the safety of using certain ARV drugs around the time of conception or during pregnancy or about the need for dosing changes during pregnancy, when relevant, because studies in pregnancy are limited. **It is important to emphasize that a lack of data does not indicate the absence or presence of risk; rather, it means that we do not have all the information about the possible effects when using these drugs during pregnancy.**

- When discussing the risks of birth defects with ARV medication exposure, it is important to point out the overall risk of defects in the general population and explain during which weeks of gestation the fetus is at risk for developing that defect. For example, a background risk of neural tube defects (NTDs) exists, regardless of the ARV regimen used or a person's HIV status during pregnancy. Most NTDs occur before the neural tube closes at 4 weeks postconception (approximately 6 weeks after the last menstrual period), often before a person is known to be pregnant. After 6 weeks' gestation, the additional risk of NTDs developing is thought to be much less likely. Folic acid supplementation should be encouraged for all people trying to conceive and in early pregnancy (see Prepregnancy Counseling and Care for Persons of Childbearing Age With HIV.
- Explain that changes in ART during pregnancy can lead to an increase in viral load, which increases the risk of perinatal HIV transmission; this viral rebound may affect choices for future ARV regimens because of the possible development of drug resistance.
- Counsel individuals who are receiving ARVs that are not *Preferred* or *Alternative* options for use during pregnancy about the benefits and risks of continuing their current ART or switching to another ARV regimen.
    - In most cases, pregnant people with HIV can continue their current regimen 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 of <50 copies/mL or less than the lower limits of detection of the assay).
    - When individuals are receiving ARVs with insufficient data about use in pregnancy (e.g., bictegravir) or ARVs with pharmacokinetic (PK) changes that could lead to lower drug levels and loss of viral suppression (e.g., cobicistat-boosted regimens), discuss whether to continue the current regimen with frequent viral load monitoring or consider switching to another ARV drug or drug regimen. In making this decision, consider the tolerability of each drug, the ability to maintain viral suppression, the risk of perinatal HIV transmission, and the risk of potential adverse outcomes. For additional information see Table 7 and People With HIV Who Are Taking Antiretroviral Therapy When They Become Pregnant.

Clinicians are encouraged to report all cases of ARV drug exposure during pregnancy or in people who conceived while receiving ARV drugs to the Antiretroviral Pregnancy Registry.

Antiretroviral Drugs That Are Recommended for Use in Pregnancy

- When making recommendations about the use of ARV drugs in pregnancy, the Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission considers available data from multiple sources about efficacy; PKs; and dosing, safety, and toxicity in pregnant and nonpregnant adults. It then assigns drugs to one of the five categories listed below (see Recommendations for Use of Antiretroviral Drugs During Pregnancy: Overview).
- *Preferred* ARV drug options for use in ARV regimens for people who are pregnant or are trying to conceive include dolutegravir (DTG) or darunavir/ritonavir (DRV/r) used in combination with two *Preferred* nucleoside reverse transcriptase inhibitors (NRTIs): abacavir plus lamivudine (3TC) or emtricitabine (FTC), tenofovir disoproxil fumarate plus 3TC or FTC, or tenofovir alafenamide plus 3TC or FTC. DTG-based regimens are *Preferred* for people with early (acute or recent) HIV infection during pregnancy unless there is a history of prior exposure to long-acting cabotegravir, when a regimen of DRV/r with TDF or TAF plus FTC or 3TC is the

Preferred ART regimen pending results of genotype testing. For additional information, see Early (Acute and Recent) HIV Infection. A moderate amount of data about pregnancy outcomes and birth defects exists for each of these drugs and drug combinations. Although these data are reassuring, it is important to note that a rigorous, systematic birth surveillance program that includes large numbers of women with periconception exposure is available only for DTG and efavirenz (EFV).

- Raltegravir, atazanavir/ritonavir, EFV, and rilpivirine (RPV) are recommended as *Alternative* ARV drug options in pregnancy. *Alternative* drugs may have more limited data on use in pregnancy than *Preferred* drugs (e.g., RPV) or may be associated with more PKs, dosing, tolerability, drug interaction, or resistance concerns than those in the *Preferred* category, but they are acceptable for use in pregnancy. Zidovudine is an *Alternative* NRTI for use in pregnancy.
- Early data (n = 426) raised concerns about a possible higher rate of NTDs among infants born to mothers who received DTG at the time of conception. However, more recent data from expanded and ongoing surveillance (n = 9,460) found that the prevalence of NTDs was identical in women receiving DTG and those receiving other ARVs at the time of conception. These more recent data are reassuring that DTG use at conception does not increase the risk of birth defects.
- The risk of other adverse pregnancy outcomes, many of which are more common than birth defects, also should be discussed. ARV regimens that contain ritonavir-boosted protease inhibitors may increase the risk of preterm delivery.
- Cobicistat-boosted regimens (atazanavir/cobicistat, darunavir/cobicistat, or elvitegravir/cobicistat) are not recommended for use during pregnancy. PK studies suggest increased drug metabolism and lower therapeutic drug levels of cobicistat-boosted ARVs during pregnancy. Individuals who choose to continue one of these regimens should have more frequent viral load monitoring (i.e., every 1 to 2 months).
- To maximize ARV absorption and effectiveness, it is important to reinforce the need to check and follow the instructions for taking the regimen (e.g., taking DRV and RPV with food, spacing administration of integrase strand transfer inhibitors with antacids or divalent cation–containing vitamins, avoiding proton pump inhibitors, and spacing administration of H2 blockers with atazanavir/cobicistat). See Appendix B: Supplement: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy for instructions about dosing and administration.
- If an ARV regimen is changed during pregnancy, drugs in the new regimen should include those that are recommended for use in pregnancy (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 in Pregnant People and Nonpregnant People Who Are Trying to Conceive), and viral load should be monitored more frequently (i.e., every 1 to 2 months).
- Recommendations regarding the use of specific ARV agents or ARV regimens often change as more information on the safety, tolerability, and PK changes of these drugs in pregnancy becomes available. For additional information, see Recommendations for Use of Antiretroviral Drugs During Pregnancy: Overview, 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 in Pregnant People and Nonpregnant People Who Are Trying to Conceive , and Appendix B: Supplement: Safety and Toxicity of Individual Antiretroviral Drugs in Pregnancy.