Recommendations for the Use of Antiretroviral Drugs During Pregnancy: Overview

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Panel's Recommendations
• Pregnancy often results in exclusion from clinical trials of antiretroviral (ARV) drugs, resulting in limited data on pharmacokinetics (PK), drug safety, and the efficacy of new ARV drugs in pregnancy and lactation. However, pregnancy, lactation, or 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).** • In most cases of HIV, when antiretroviral therapy (ART) is being used at the time of presentation for pregnancy care, the current ART should be continued if the regimen is tolerated, safe, and effective in suppressing viral replication (defined as a regimen that maintains an HIV RNA level [viral load] less than the lower limits of detection of the assay) **(AII)** (see When Antiretroviral Therapy is Being Taken When Pregnancy Occurs). • If ART is not already being used, it should be initiated as early in pregnancy as possible, regardless of HIV RNA level or CD4 T lymphocyte cell count, to maximize health and prevent perinatal HIV transmission and sexual transmission **(AI).** In addition to benefiting personal health and preventing HIV transmission to sexual partners, the goal of ART during pregnancy is to achieve and maintain HIV viral suppression to undetectable levels to reduce the risk of perinatal transmission and maximize health during pregnancy **(AI).** • The selection of which ARV drugs to use during pregnancy is best made through shared decision-making between the health care 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 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. • 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: *Preferred*, *Alternative*, *Insufficient Data to Recommend*, *Not Recommended Except in Special Circumstances*, and *Not Recommended*, as outlined in 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 a variety of clinical scenarios. o When selecting ARV drugs for use in pregnancy or when trying to conceive, the Panel recommends the use of ARV drugs in the *Preferred* or *Alternative* 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 During Pregnancy and When Trying to Conceive. • When choosing an ARV drug regimen and weighing the benefits and risks of specific ARVs for use during pregnancy or when trying to conceive, providers and patients should consider multiple factors, including adverse effects, drug interactions, PK, convenience of the individual drugs and drug combinations in the regimen, available pregnancy safety and outcome data, virologic efficacy in nonpregnant adults (and during pregnancy if data are available), and the patient's resistance test results and comorbidities **(AIII).**

- Physiologic changes during pregnancy may impact the PK (absorption, distribution, metabolism, and excretion) of ARVs and lead to changes in drug concentrations and effectiveness in suppressing HIV viral replication, especially later in pregnancy when viral rebound may increase transmission risk and impact intrapartum and birth management (see Table 9 in Intrapartum HIV Care). Patients 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 When Antiretroviral Therapy is Being Taken When Pregnancy Occurs).
- 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 Prepregnancy Counseling and Care and Postpartum HIV Management and Follow-Up for more information.
- Clinicians are encouraged to submit to the Antiretroviral Pregnancy Registry data any time ARV drugs are being used during pregnancy or when conception occurs **(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*

Selection of Antiretroviral Drugs During Pregnancy

Selection of antiretroviral (ARV) drugs **should be individualized** for HIV during pregnancy or when trying to conceive. The availability of data about the use of each medication in pregnancy is a primary consideration. In addition, durability, tolerability, and simplicity of a medication regimen are particularly important for ensuring adherence and preserving future treatment options. Regimen selection should be based on several factors that apply during all pregnancies, as well as factors that will vary for individuals.

Pregnancy-related factors include potential short-term and long-term adverse effects on fetuses or newborns, such as possible risk of teratogenicity, preterm birth, or effects on growth and development, and the degree to which data are available about these risks; pharmacokinetic (PK) changes in pregnancy; and potential adverse effects for maternal health, especially those that may be exacerbated during pregnancy.

Individual-level factors, if applicable, should be considered when selecting ARVs. Factors to consider include potential ARV drug interactions with other medications; results of resistance testing and prior exposure to ARV drugs; comorbidities; ability of the patient to tolerate and adhere to a regimen; and convenience and individual preference. A preference for antiretroviral therapy (ART) during pregnancy may require balancing known and unknown risks and benefits. This section provides an overview of the key clinical and PK issues that are relevant to the selection of specific ARV drugs for use in pregnancy.

After reviewing key concepts about balancing the risks and benefits and PK, this section will define the categories of ARV drug recommendations in pregnancy: *Preferred, Alternative, Insufficient Data, Not Recommended Except in Special Circumstances,* and *Not Recommended*. Whenever possible, ARV drugs that are *Preferred* for use in pregnancy should be used. However, it is important to note that ART for HIV is usually being used when pregnancy occurs and often *Preferred* or *Alternative* ARV drugs are being used.[1]

The sections that follow focus on the benefits of ART and recommendations for the use of ARV drugs in specific scenarios:

- Use of Antiretroviral Drugs to Prevent Perinatal HIV Transmission and Improve Health During Pregnancy
- Antiretroviral Therapy When Trying to Conceive
- Initial Use of Antiretroviral Therapy During Pregnancy
- When Antiretroviral Therapy is Being Taken When Pregnancy Occurs
- Previous Experience With Antiretroviral Medications but Not on Antiretroviral Therapy During Current Pregnancy
- Lack of Viral Suppression While on Antiretroviral Therapy in Pregnancy
- Discontinuation of ART (see Discontinuation of ART below)

Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy When Antiretroviral Therapy Has Never Been Received provides advantages and disadvantages of specific ARV drugs and drug combinations in pregnancy, focusing primarily on considerations when ARV drugs have never been used, with additional information about other clinical scenarios.

Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs During Pregnancy and When Trying to Conceive for a variety of clinical scenarios consolidates these scenario-specific recommendations for the use of ARV drugs for HIV when trying to conceive or during pregnancy into a single table for ease of reference.

Table 14. Antiretroviral Drug Use in Pregnancy: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy and Appendix B: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy provide information about individual drugs, including dosing and PK data in pregnancy.

For recommendations about the use of ARV drugs when there is childbearing potential but pregnancy is not currently desired, see the Adult and Adolescent Antiretroviral Guidelines.

Balancing Risks and Benefits of ART in the Face of Limited Data

The selection of which ARV drugs to use during pregnancy or when trying to conceive is best made through **shared decision-making** between the patient and the health care provider following comprehensive discussion of the known benefits, as well as potential risks to maternal and fetal health[2] (see Appendix C: Antiretroviral Counseling Guide for Health Care Providers). Data about the PK, teratogenicity, and safety of individual ARV drugs during pregnancy are provided in Appendix B: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy.

During discussions, it can be helpful to point out that **ARV regimens taken during pregnancy can be modified after delivery.** After delivery, some regimens that could not be used during pregnancy due to insufficient or problematic safety and/or PK data may be able to be used. These decisions should take several factors into consideration, including the current ART recommendations for nonpregnant adults and adolescents, the patient's plans for contraceptive use and future pregnancies, and individual adherence considerations and medication preferences (see the Adult and Adolescent Antiretroviral Guidelines and Postpartum HIV Management and Follow-Up).

Pregnancy often results in exclusion from clinical trials of ARV drugs. As a result, data regarding the PK, drug safety, and efficacy of new ARV drugs often are limited to nonpregnant adults.[3,4]

Information about the efficacy of ARV drugs for treatment of HIV in pregnancy can be extrapolated from evidence of efficacy in nonpregnant adults, as long as direct PK evaluation in pregnancy demonstrates drug exposures in pregnancy that are within the effective range in nonpregnant adults. Similarly, ART regimens that result in viral suppression throughout pregnancy are likely to be effective in preventing perinatal transmission of HIV. To expedite the investigation of new ARV drugs during pregnancy, it is essential that studies evaluate the PK of these drugs during pregnancy as soon as possible after dosing in nonpregnant people is established. There is a median delay of 6 years between the registration of new ARVs and the first published PK data in pregnancy.[5] In addition, clinical trials should carefully evaluate the safety of ARV drugs in the setting of childbearing potential, and measurement of efficacy should be included as a secondary endpoint in pregnancy.[6]

Drugs with known benefits to people who are not pregnant should not be withheld during pregnancy unless they have known adverse effects for maternal, fetal, or infant health and these adverse effects outweigh the maternal benefits or adequate drug levels are not likely to be attained during pregnancy. Pregnancy or the potential for pregnancy **should not preclude** the use of optimal drug regimens.

It is important for providers to counsel about the clear benefits of ART for maternal health and prevention of HIV transmission to the infant and sexual partners, as well as the limitations of available data on individual drugs.[7] Data about the benefits of ART are summarized and discussed in recommendations for the Use of Antiretroviral Drugs to Prevent Perinatal HIV Transmission and Improve Health During Pregnancy. Overall, data are limited on the risks associated with using *Preferred* and *Alternative* ARV drugs other than tenofovir disoproxil fumarate, emtricitabine, lamivudine, efavirenz (EFV), and dolutegravir (DTG) during preconception or in very early pregnancy. Importantly, this **lack of data indicates neither the presence nor the absence of risk.** For more details and information about other drugs, please see Teratogenicity, Antiretroviral Drug Regimens and Pregnancy Outcomes, Appendix C: Antiretroviral Counseling Guide for Health Care Providers, and Appendix B: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy.

Preterm Birth and Other Adverse Pregnancy Outcomes

The risk of other adverse pregnancy outcomes that are more common than birth defects also should be considered when selecting ART regimens (see Antiretroviral Drug Regimens and Pregnancy Outcomes). For example, the use of some protease inhibitors (PIs), particularly lopinavir/ritonavir (no longer recommended), has been associated with an increased risk of preterm birth, which may lead to an increase in infant morbidity and mortality.[8-10]

Maternal Health Outcomes

Data on maternal health outcomes (e.g., gestational hypertension, weight gain) with ART use during pregnancy, particularly with newer ART regimens, are needed (see Antiretroviral Drug Regimens and Pregnancy Outcomes).[11-14]

Data on the association between ART and hypertensive disorders in pregnancy are limited; some studies demonstrated an elevated incidence in pregnant people with HIV, but other studies have shown no difference.[14] A U.S.-based cohort of pregnant people with HIV who were on ART found that nearly 20% had hypertensive disorders of pregnancy, composed of about 50% chronic and 50% new-onset hypertension.[15] The incidence of new-onset hypertension was higher among pregnant people initiating ART on or after 20 weeks of gestation compared to those starting ART before conception and in those with low CD4 T lymphocyte cell count. Meanwhile, ARV class was not associated with hypertensive disorders.

Substantial weight gain on DTG-based regimens has been observed in nonpregnant populations, especially among women and people also receiving tenofovir alafenamide (see Dolutegravir and Tenofovir Alafenamide).[16,17] However, it is difficult to extrapolate data about weight gain in nonpregnant adults to determine the effects of ARV drugs on gestational weight gain. DTG-associated weight gain has been observed in pregnancy, but this may reflect better maternal health (e.g., lower rates of insufficient weight gain or weight loss during pregnancy with DTG-based ART). Data on weight gain during pregnancy with DTG-based ART are mixed. Some data from African studies suggest that there may be more weight gain with DTG-based ART than with EFV-based ART during pregnancy[18,19]; however, the weight gain observed with DTG was less than the weight gain observed in pregnant people without HIV and less than the recommended weight gain in pregnancy for the general population.[19,20] A study in the United States found that gestational weight gain was not associated with ARV class, but weekly weight gain in the second and third trimesters was greater in pregnant people who were overweight or obese when entering pregnancy and received integrase strand transfer inhibitors (INSTIs).[20]

Pharmacokinetic Considerations for ARV Drugs

Physiologic changes in pregnancy can affect drug absorption, distribution, metabolism, and elimination, thereby affecting requirements for drug dosing and potentially increasing the risk for virologic failure or drug toxicity.[21-23] During pregnancy, gastrointestinal transit time is prolonged, and body water and fat increase throughout gestation. These changes are accompanied by increases in cardiac output, ventilation rate, and liver and renal perfusion. Plasma protein concentrations also decrease, which can reduce the total plasma drug levels but not necessarily the free or unbound plasma drug levels. Furthermore, renal sodium reabsorption increases, and changes occur in cellular transporters and drug metabolizing enzymes in the liver and intestine. Placental transport of drugs, compartmentalization of drugs in the embryo/fetus and placenta, biotransformation of drugs by the fetus and placenta, and elimination of drugs by the fetus can also affect drug PK in the pregnancy.

In general, the PK of nucleoside reverse transcriptase inhibitors and non-nucleoside reverse transcriptase inhibitors (NNRTIs) are similar in pregnancy and in nonpregnant people (although PK data for some drugs are limited or not available). The PK of PIs and INSTIs are more variable, particularly during the second and third trimesters. Because dosing may differ in pregnancy, clinicians should review the currently available data on the PK and dosing of ARV drugs in pregnancy (see Appendix B: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy and Table 14. Antiretroviral Drug Use in Pregnancy: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy) and information about how PK changes affect recommendations for use of specific ARV drugs in pregnancy (see Categories for Drug Recommendations in Pregnancy below, 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).

Categories of Drug Recommendations in Pregnancy

The Panel assigns U.S. Food and Drug Administration–approved ARV drugs to one of five categories, described below, for use in pregnancy. Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy When Antiretroviral Therapy Has Never Been Received lists all ARV drugs and drug combinations and summarizes advantages and disadvantages of each. Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs During Pregnancy and When Trying to Conceive provides an overview of Panel recommendations for ARV drugs in different clinical scenarios that are described in the following sections: Antiretroviral Therapy When Trying to Conceive, When Antiretroviral Therapy is Being Taken When Pregnancy Occurs, Previous Experience With Antiretroviral Medications but Not on Antiretroviral Therapy During Current

Pregnancy, and Lack of Viral Suppression While on Antiretroviral Therapy in Pregnancy. It is important for health care providers to read all the information on each drug in the Perinatal Guidelines before administering any of these HIV medications during pregnancy (see Appendix B: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy) and provide appropriate counseling to support informed shared decision-making (see Appendix C: Antiretroviral Counseling Guide for Health Care Providers).

- **Preferred:** Drugs or drug combinations are designated as *Preferred* for therapy in pregnancy when clinical trial data in nonpregnant adults have demonstrated efficacy and durability with acceptable toxicity and ease of use and when pregnancy-specific PK data are available to guide dosing. In addition, the available data must suggest a favorable risk-benefit balance for the drug or drug combination compared with other ARV drug options; this assessment of risks and benefits should incorporate outcomes for maternal, fetal, and infant health. Some *Preferred* drugs or regimens may have minimal toxicity or incompletely evaluated teratogenicity risks that are offset by other advantages during pregnancy or when trying to conceive.
- **Alternative:** Drugs or drug combinations are designated as *Alternative* options for therapy in pregnancy when clinical trial data in nonpregnant adults show efficacy and the data in pregnancy are limited but generally favorable. Most *Alternative* drugs or regimens are associated with more PK, dosing, tolerability, formulation, administration, or interaction concerns than those in the *Preferred* category, but they are acceptable for use in pregnancy. Some *Alternative* drugs or regimens may have known risks that are offset by other advantages during pregnancy or when trying to conceive.
- **Insufficient Data to Recommend:** The drugs and drug combinations in this category are approved for use in nonpregnant adults, but pregnancy-specific PK or safety data are too limited to make a recommendation for use in pregnancy. In some cases, it may be appropriate to continue using these drugs or drug combinations when ART that has been well tolerated is used when pregnancy occurs.
- **Not Recommended Except in Special Circumstances:** Although some drugs are not recommended for initial ART when ART has never been used because of specific safety concerns or very limited safety and efficacy data in pregnancy, there may be circumstances in the context of ART experienced when initiation or continuation of specific drugs is needed to reach or maintain viral suppression.
- **Not Recommended:** Drugs and drug combinations listed in this category are not recommended for use in pregnancy because of inferior virologic efficacy or potentially serious maternal or fetal safety concerns. This category includes drugs or drug combinations for which PK data demonstrate low drug levels and risk of viral rebound during pregnancy. Levels of these drugs are often low in late pregnancy (during the second and third trimesters), when risk for perinatal transmission is high if viremia occurs during pregnancy.

In some situations, it may be appropriate to continue using drugs or drug combinations designated as *Insufficient Data, Not Recommended Except in Special Circumstances,* or *Not Recommended* when fully suppressive ART that has been well tolerated is used when pregnancy occurs, although viral load monitoring and, in some cases, safety monitoring should be performed more frequently in these instances. See When Antiretroviral Therapy is Being Taken When Pregnancy Occurs and Initial Evaluation and Continued Monitoring of HIV During Pregnancy.

In assigning these categories, the Panel uses information from several sources to develop recommendations on specific drugs or regimens for use during pregnancy. These sources include—

- Data from randomized clinical trials and prospective cohort studies that demonstrate durable viral suppression in pregnancy, as well as immunologic and clinical improvement;

- Incidence rates and descriptions of short-term and long-term drug toxicity of ARV regimens;
- Evidence from clinical studies on the risk of maternal toxicity, teratogenicity, adverse pregnancy outcomes, and adverse infant outcomes;
- Specific knowledge about drug tolerability and simplified dosing regimens;
- Known efficacy of ARV drug regimens in reducing perinatal transmission of HIV when data are available, evidence of high rates of viral suppression during pregnancy, or evidence of high rates of viral suppression in nonpregnant people with PK (drug exposure) data in pregnancy demonstrating exposures similar to those in nonpregnant people;
- PK (drug exposure) data during pregnancy;
- Data from animal teratogenicity studies; *and*
- Antiretroviral Pregnancy Registry data and other postmarketing surveillance data.

Discontinuation of ART

The Panel strongly recommends against discontinuing ART during pregnancy. However, if an ARV drug regimen must be stopped for any reason, all ARV drugs should be stopped simultaneously. ART should be reinitiated as soon as possible, whether the same regimen is restarted or a new regimen is initiated during pregnancy. If an ARV drug that is known to have a long serum half-life (e.g., NNRTIs) must be stopped for more than a few days, clinicians should consider assessing for rebound viremia after a new regimen is started and viral suppression would be expected; if optimal viral suppression has not been achieved, potential drug resistance should be assessed (see Antiretroviral Drug Resistance and Resistance Testing in Pregnancy).[24]

Temporary discontinuation of ARV drug regimens during pregnancy may be indicated in some situations, including cases of serious drug-related toxicity, pregnancy-induced hyperemesis that is unresponsive to antiemetics, or acute illnesses or planned surgeries that prevent oral medications from being used. Possible toxicity or intolerance to a single ARV agent should prompt discussion about options for modifying rather than stopping an entire ARV regimen (see When Antiretroviral Therapy is Being Taken When Pregnancy Occurs).[24]

Discontinuation of therapy could lead to an increase in viral load, with possible disease progression and decline in immune status during the pregnancy and increased risk of *in utero* transmission of HIV. An analysis from a prospective cohort of 937 mother–child pairs from the Italian Register for HIV Infection in Children found that interruption of ART during pregnancy, including interruption in the first and third trimesters, was independently associated with an increased rate of perinatal HIV transmission.[25] Although the perinatal transmission rate for the entire cohort was only 1.3%, transmission occurred in 4.9% of mother–child pairs with first-trimester interruption (95% confidence interval [CI], 1.9% to 13.2%; adjusted odds ratio [aOR] 10.33; $P = 0.005$) and 18.2% of mother–child pairs with third-trimester interruption (95% CI, 4.5% to 72.7%; aOR 46.96; $P = 0.002$).[25]

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