Initial Evaluation and Continued Monitoring of HIV During Pregnancy

Updated: January 31, 2024
Reviewed: January 31, 2024

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 planned 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 and have CD4 counts of <300 cells/mm³, those with inconsistent adherence, or those with detectable viral loads should have CD4 counts monitored every 3 months during pregnancy; patients on ART <2 years and with CD4 counts ≥300 cells/mm³ should have CD4 monitored every 6 months (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 (AII).

- Pregnant people with HIV who are taking ART during pregnancy should undergo standard gestational diabetes screening (AIII). Some experts suggest performing this screening early in pregnancy for those who may be at high risk for gestational diabetes on protease inhibitor–based ART (CIII).

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

Viral Load and CD4 Cell Count Testing and Monitoring

Viral loads should be monitored more frequently in pregnant individuals than in nonpregnant individuals because of the importance of rapid and sustained viral suppression through delivery in preventing perinatal HIV transmission (see Table 5 below). Individuals who are adherent to their
antiretroviral therapy (ART) and who do not harbor resistance mutations to the prescribed drugs should generally achieve viral suppression within 3 to 12 weeks on preferred regimens, such as integrase inhibitor–based ART, depending on the initial viral load. Individuals with higher viral loads and lower CD4 T lymphocyte (CD4) cell counts are more likely to require more time to achieve viral suppression than those with lower viral loads and higher CD4 counts. Those using integrase strand transfer inhibitors (INSTIs) are more likely to achieve suppression in much shorter time frames. Most patients with adequate viral response at 24 weeks of treatment have had at least a 1 log₁₀ viral load decrease within 1 to 4 weeks after starting therapy.

Viral load should be monitored in pregnant patients with HIV at the initial clinic visit with a review of prior viral load levels 2 to 4 weeks after initiating or changing ART, monthly until undetectable, and at least every 3 months thereafter. If adherence is a concern, especially during early pregnancy, more frequent monitoring is recommended because of the increased risk of perinatal HIV transmission associated with detectable HIV viremia during pregnancy. Similarly, pregnancy may reduce the drug exposure levels or the efficacy of some drugs; patients who are taking these drugs may require a change in therapy or more frequent viral load monitoring (see Table 6 and Table 7). More frequent viral load monitoring is recommended for those who are receiving regimens containing rilpivirine or cobicistat-boosted elvitegravir, atazanavir, or darunavir. Although increasing the frequency of viral load monitoring may help detect viral rebound, this may be difficult to implement if visit attendance or access to viral load monitoring is limited. In addition, viremia detected in late pregnancy may be challenging to manage, requiring medication changes shortly before delivery (see People with HIV Who Are Taking Antiretroviral Therapy When They Become Pregnant).

Viral load also should be assessed at approximately 36 weeks gestation, or within 4 weeks of planned delivery, to inform decisions about the mode of infant delivery and optimal treatment for newborns (see Intrapartum Care for People with HIV).

In pregnant patients with HIV, CD4 count should be measured at the initial clinic visit with a review of prior CD4 counts (see Table 5 below). For patients who have been on ART for ≥2 years, have had consistent viral suppression and CD4 counts that are consistently >300 cells/mm³, and are tolerating ART during pregnancy, CD4 count should be monitored only at the initial antenatal visit; CD4 counts do not need to be repeated for these patients during this pregnancy, per the Adult and Adolescent Antiretroviral Guidelines. Patients who have been on ART for <2 years and have CD4 counts of <300 cells/mm³, those with inconsistent adherence, or those with detectable viral loads should have CD4 counts monitored every 3 months during pregnancy. Patients who have been on ART <2 years and have CD4 counts of ≥300 cells/mm³ should have CD4 counts monitored every 6 months. The safety of this approach is supported by research that demonstrates that patients who are stable on ART (defined as patients who have viral load levels <50 copies/mL and CD4 counts >500 cells/mm³ for at least 1 year) are highly unlikely to experience a CD4 count <350 cells/mm³ in the span of a year.

**HIV Drug–Resistance Testing**

HIV drug–resistance testing should be reviewed in conjunction with ARV history if prior results are available and performed in pregnant patients with HIV before starting or modifying ART if HIV RNA levels are above the threshold for standard 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) (see Table 5 below). Genotypic testing should be performed. In cases of treatment-experienced
individuals with suspected multidrug resistance and who are on failing regimens, phenotypic testing also should be performed. See Drug-Resistance Testing in the Adult and Adolescent Antiretroviral Guidelines and Antiretroviral Drug Resistance and Resistance Testing in Pregnancy for more information on resistance testing, including considerations regarding INSTI genotypic resistance testing. ART should not be delayed while waiting for resistance test results. If the results demonstrate resistance, then the regimen can be adjusted subsequently. HIV drug–resistance testing also should be performed on patients who are on ART but have suboptimal viral suppression (i.e., failure to achieve undetectable levels of virus during an appropriate time frame, as noted above) or sustained viral rebound to detectable levels after prior viral suppression on ART (see Pregnant People Who Have Not Achieved Viral Suppression on Antiretroviral Therapy and Antiretroviral Drug Resistance and Resistance Testing in Pregnancy). Drug-resistance testing in the setting of virologic failure is most useful when it is performed while patients are receiving ARV drugs or within 4 weeks after discontinuing drugs. Even if more than 4 weeks have elapsed since the ARV drugs were discontinued, resistance testing can still provide useful information to guide therapy, although it may not detect all resistance mutations that were selected by previous ARV regimens.

Other Laboratory Testing and Monitoring

The laboratory tests that are assessed initially and used to monitor complications of ARV drugs during pregnancy should be chosen based on what is known about the adverse effects of the drugs a patient is receiving (see Table 5 below). For example, HLA-B*5701 testing should be performed if the use of abacavir is anticipated. Routine hematologic monitoring is recommended for patients who are receiving zidovudine-containing regimens, and routine renal monitoring is recommended for patients who are receiving tenofovir-containing regimens. Liver function should be monitored in all patients who are receiving ART, ideally within 2 to 4 weeks after initiating or changing ARV drugs and approximately every 3 months thereafter or as needed for other clinical care. Hepatic dysfunction has been observed in pregnant women on protease inhibitors (PIs), and the use of any PI during pregnancy has been associated with higher rates of liver function test abnormalities than the rates observed with non-nucleoside reverse transcriptase inhibitor–based ART. Pregnant women in general are more likely than their nonpregnant counterparts to have elevated levels of liver enzymes.

Pregnancy itself increases the risk of glucose intolerance. In a meta-analysis, the pooled prevalence of gestational diabetes among women with HIV was 4.42% (95% confidence interval, 3.48% to 5.35%). These rates do not appear to be higher than those in non-HIV populations. The majority of studies in pregnant women have not demonstrated an association between HIV infection and gestational diabetes. However, other studies, particularly those with stringent definitions of gestational diabetes, did show an increased risk of gestational diabetes in women who were taking PI-based regimens during pregnancy. In addition, one study and several case series in nonpregnant adults with HIV have reported an increased risk for incident diabetes after initiation of INSTIs. Patients with HIV who are on ART during pregnancy should receive the standard screening for gestational diabetes that is recommended for all pregnant people. However, some experts suggest performing this screening earlier in pregnancy for patients who are receiving PI-based ART that was initiated before pregnancy, in accordance with recommendations for patients with risk factors for glucose intolerance, such as obesity (see Table 5 below).

In addition to gestational diabetes risk with some ARV classes, risk for weight gain and obesity both during pregnancy and postpartum may be present with integrase inhibitor use, although existing evidence is somewhat inconclusive, with most published data collected in nonpregnant populations (see Considerations for Antiretroviral Use in Special Patient Populations in the...
Several studies in nonpregnant people with HIV have reported higher weight gain with the combined use of tenofovir alafenamide and integrase inhibitors,\textsuperscript{45,51,52} with another study in pregnant people with HIV observing a similar finding.\textsuperscript{53} Current guidelines from the American College of Obstetricians and Gynecologists and the National Academy of Medicine recommend that appropriate weight gain, diet, and exercise during pregnancy should be discussed with patients at initial antenatal visits and regularly thereafter.\textsuperscript{54-56}
Table 5. HIV-Related Laboratory Monitoring Schedule for Pregnant People with HIV

<table>
<thead>
<tr>
<th>Laboratory Test</th>
<th>Timepoint or Frequency of Testing</th>
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</thead>
<tbody>
<tr>
<td>HIV RNA Levels$^b$</td>
<td>At Approximately 36 Weeks of Gestation or Within 4 Weeks of Planned Delivery to Inform Mode of Delivery and Infant ARV Regimen</td>
</tr>
<tr>
<td>CD4 Count$^e$</td>
<td></td>
</tr>
</tbody>
</table>

- **Entry Into Antenatal Care$^c$**: ✓
- **ART Initiation or Modification**: ✓
- **2 to 4 Weeks After ART Initiation or Modification**: ✓
- **Monthly**: ✓
- **Every 3 Months During Pregnancy**: ✓
- **At 24 to 28 Weeks Gestation**: ✓
- **At Approximately 36 Weeks of Gestation or Within 4 Weeks of Planned Delivery to Inform Mode of Delivery and Infant ARV Regimen**: ✓

- **HIV RNA Level**:
  - If a result is not available within 2 weeks of ART initiation or modification:
  - Until HIV RNA levels are undetectable:
  - At least every 3 months$^d$

- **CD4 Count**:
  - Patients who have been on ART for <2 years and have CD4 counts of <300 cells/mm$^3$, those with inconsistent adherence, or those with detectable viral loads should have CD4 counts monitored every
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<table>
<thead>
<tr>
<th>Laboratory Test</th>
<th>Entry Into Antenatal Care</th>
<th>ART Initiation or Modification</th>
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<tbody>
<tr>
<td>Resistance Testingf</td>
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<td>3 months during pregnancy.²</td>
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<td>HLA-B*5701 Testing</td>
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<tr>
<td>Standard Screening for Gestational Diabetesg</td>
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<tr>
<td>Complete Blood Cell Count; Renal Function</td>
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</table>

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

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<tbody>
<tr>
<td></td>
<td>Entry Into Antenatal Care&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>Liver Function</td>
<td>✓</td>
</tr>
<tr>
<td>Monitoring for ARV-Specific Toxicities&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Refer to the recommendations in the package inserts for the individual ARV drugs.</td>
</tr>
</tbody>
</table>

<sup>a</sup> For additional information, see Laboratory Monitoring in the Adult and Adolescent Antiretroviral Guidelines.

<sup>b</sup> 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). Obtain an HIV RNA level at the time of ART initiation or modification if a recent result within 2 weeks prior is not available.

<sup>c</sup> Prior HIV-related illnesses and past plasma HIV RNA levels and CD4 counts should be reviewed at entry into antenatal care.

<sup>d</sup> More frequent viral load monitoring (every 1–2 months) may be indicated for patients who are taking ARVs that have been shown to have reduced drug levels in the second and third trimesters (e.g., cobicistat, elvitegravir, rilpivirine) and are potentially at risk for loss of viral suppression (see Table 6, Table 7, and People with HIV Who Are Taking Antiretroviral Therapy When They Become Pregnant).

<sup>e</sup> CD4 count should be measured at the initial antenatal visit (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/mm<sup>3</sup> 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 and have CD4 counts of <300 cells/mm<sup>3</sup>, those with inconsistent adherence, or those with detectable...
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- viral loads should have CD4 counts monitored every 3 months during pregnancy (CIII). Those on ART<2 years and with CD4 counts >300 cells/mm³ should have CD4 monitored every 6 months.

- ARV drug-resistance testing (genotypic testing and, if indicated, phenotypic testing) should be performed in patients whose HIV RNA levels are above the threshold for standard 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 performed before—
  - Initiating ART in ARV-naive pregnant patients who have not been tested previously for ARV drug resistance (AII);
  - Initiating ART in ARV-experienced pregnant patients (AIII); or
  - Modifying ARV regimens for patients who become pregnant while receiving ARV drugs or patients who have suboptimal virologic response to ARV drugs that were started during pregnancy (AII).

- 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 the resistance tests (BIII).

- Patients who are taking ART during pregnancy should undergo standard gestational diabetes screening (AIII). Some experts suggest performing glucose screening early in pregnancy for patients who are receiving PI-based regimens that were initiated before pregnancy, in accordance with recommendations for patients who are at risk for glucose intolerance (BIII). For more information on PIs, see Antiretroviral Drug Regimens and Maternal and Neonatal Outcomes.

- Laboratory testing to monitor complications of ARV drugs during pregnancy should be based on what is known about the adverse effects of the drugs a person is receiving (AIII).

**Key:** ART = antiretroviral therapy; ARV = antiretroviral; CD4 = CD4 T lymphocyte

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

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