

## Initial Evaluation and Continued Monitoring of HIV-Related Assessments During Pregnancy

Updated: January 31, 2023

Reviewed: January 31, 2023

### 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 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  $\geq 2$  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, patients with CD4 counts  $<300$  cells/mm<sup>3</sup>, and patients with inconsistent adherence and/or detectable viral loads should have CD4 counts monitored every 3 months during pregnancy **(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  $\leq 500$  copies in some laboratories). Testing should be conducted before—
  - Initiating ART in ARV-naïve 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 **(AIII)**.
- Pregnant people with HIV who are taking ART during pregnancy should undergo standard glucose screening **(AIII)**. Some experts suggest performing glucose screening early in pregnancy for those who **may be at high risk for gestational diabetes on protease inhibitor–based ART (BIII)**. For more information on ART, see [Antiretroviral Drug Regimens and Maternal and Neonatal Outcomes](#).

**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 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 achieve viral suppression within **4 to 12** weeks. Individuals with higher viral loads and lower CD4 T lymphocyte (CD4) cell counts are more likely to require more time to achieve viral suppression<sup>1,2</sup> than those with lower viral loads and higher CD4 counts. In addition, those using integrase strand transfer inhibitors (INSTIs) are more likely to achieve suppression in much shorter time frames.<sup>3-5</sup> Most patients with adequate viral response at 24 weeks of treatment have had at least a 1 log<sub>10</sub> viral load decrease within 1 to 4 weeks after starting therapy.<sup>6,7</sup>

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.<sup>8-10</sup> 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 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  $\geq 2$  years, have had consistent viral suppression and CD4 counts that are consistently  $>300$  cells/mm<sup>3</sup>, 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](#).<sup>6,11,12</sup> Patients who have been on ART for  $< 2$  years, patients with CD4 counts of  $< 300$  cells/mm<sup>3</sup>, and those with inconsistent adherence and/or detectable viral loads should have CD4 counts monitored every 3 months during pregnancy. 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/mm<sup>3</sup> for 1 year) are highly unlikely to experience a CD4 count  $< 350$  cells/mm<sup>3</sup> in the span of a year.<sup>13</sup>

## ***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 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 taking ART but who have suboptimal viral suppression (i.e., failure to achieve undetectable levels of virus during an appropriate time frame, as noted above) or who have 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](#).<sup>14-18</sup> 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.<sup>19-21</sup>

Pregnancy itself increases the risk of glucose intolerance. In a recent 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.<sup>22,23</sup> The majority of studies in pregnant women have not demonstrated an association between HIV infection and gestational diabetes,<sup>24-28</sup> although some studies with stringent definitions of gestational diabetes did show an increased risk of gestational diabetes in women who were taking PI-based regimens during pregnancy.<sup>29</sup> 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](#).<sup>30-34</sup> Patients with HIV who are on ART during pregnancy should receive the standard glucose screening that is recommended for all pregnant women. However, some experts would perform glucose 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).<sup>35</sup>

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.<sup>36-43</sup> Current guidelines from the American College of Obstetricians and Gynecologists as well as 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.<sup>44,45</sup>

**Table 5. HIV-Related Laboratory Monitoring Schedule for Pregnant People With HIV<sup>a</sup>**

Laboratory Test	Timepoint or Frequency of Testing						
	Entry Into Antenatal Care <sup>c</sup>	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 delivery to Inform Mode of Delivery and Infant ARV Regimen
HIV RNA Levels <sup>b</sup>	✓ <sup>c</sup>	✓ 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 <sup>d</sup>		✓
CD4 Count <sup>e</sup>	✓ <sup>c</sup>				✓ For patients who have been on ART for <2 years, patients with CD4 counts <300 cells/mm <sup>3</sup> , and patients with inconsistent adherence and/or detectable viral loads		

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Resistance Testing <sup>f</sup>		✓					
HLA-B* 5701 testing		✓ If abacavir use anticipated					
Standard Glucose Screening <sup>g</sup>						✓	
Complete Blood Cell Count; Renal Function	✓	✓ With additional testing as clinically indicated				✓	
Liver Function	✓	✓			✓ With additional testing as clinically indicated		
Monitoring for ARV-	Refer to the recommendations in the package inserts for the individual ARV drugs.						

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Specific Toxicities <sup>h</sup>							

<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 cell 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](#) and [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  $\geq 2$  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, patients with CD4 counts  $<300$  cells/mm<sup>3</sup>, and patients with inconsistent adherence and/or detectable viral loads should have CD4 counts monitored every 3 months during pregnancy **(CIII)**.

<sup>f</sup> 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  $\leq 500$  copies in some laboratories**). Testing should be performed before—

- Initiating ART in ARV-naïve pregnant patients who have not been tested previously for ARV drug resistance **(AII)**;
- Initiating ART in ARV-experienced pregnant patients **(AIII)**; or

## Table 5. HIV-Related Laboratory Monitoring Schedule for Pregnant People With HIV

- 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 resistance testing **(BIII)**.

<sup>g</sup> Patients who are taking ART during pregnancy should undergo standard glucose 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 [Combination Antiretroviral Drug Regimens and Maternal and Neonatal Outcomes](#).

<sup>h</sup> 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 woman is receiving **(AIII)**.

Key: ART = antiretroviral therapy; ARV = antiretroviral; CD4 = CD4 T lymphocyte; LFT = liver function test; PI = protease inhibitor



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