Monitoring of the Woman and Fetus During Pregnancy

(Last updated December 29, 2020; last reviewed December 29, 2020)

Panel's Recommendations
• The plasma HIV RNA levels of pregnant women with HIV should be monitored at the initial antenatal visit **(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 34 to 36 weeks gestation to inform decisions about mode of delivery (see Intrapartum Care for Women 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 **(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)**. Women who have been on ART for <2 years, women with CD4 counts <300 cells/mm^3, and women 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 performed in women whose HIV RNA levels are above the threshold for standard resistance testing (i.e., >500 copies/mL to 1,000 copies/mL) before—
  • Initiating ART in antiretroviral (ARV)-naive pregnant women who have not been previously tested for ARV drug resistance (AII);
  • Initiating ART in ARV-experienced pregnant women **(AIII)**; *or*
  • Modifying ARV regimens for women who become pregnant while receiving ARV drugs or women who have suboptimal virologic response to ARV drugs that were started during pregnancy **(AII)**.

• ART should be initiated in pregnant women prior to receiving the results of ARV-resistance tests. ART should be modified, if necessary, based on the results of resistance testing **(BIII)**.
• 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)**.
• Women who are taking ART during pregnancy should undergo standard glucose screening **(AIII)**. Some experts suggest performing glucose screening early in pregnancy for women who are receiving protease inhibitor (PI)-based regimens that were initiated before pregnancy, in accordance with recommendations for women who are at risk for glucose intolerance **(BIII)**. For more information on PIs, see Combination Antiretroviral Drug Regimens and Maternal and Neonatal Outcomes.
• Amniocentesis, if clinically indicated, should be performed on women with HIV only after initiation of an effective ARV regimen and, ideally, when HIV RNA levels are undetectable **(BIII)**. If a woman with detectable HIV RNA levels requires amniocentesis, consultation with an expert in the management of HIV during pregnancy should be considered **(BIII)**.
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 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 6 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 8 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[1,2] 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.[3–5] Most patients with adequate viral response at 24 weeks of treatment have had at least a 1 $\log_{10}$ viral load decrease within 1 to 4 weeks after starting therapy.[6,7] Viral load should be monitored in pregnant women with HIV at the initial clinic visit, 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.[8–10] Similarly, pregnancy may reduce the drug exposure levels or the efficacy of some drugs; women who are taking these drugs may require a change in therapy or more frequent viral load monitoring (see Table 4 and Table 5). More frequent viral load monitoring is recommended for women 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 Pregnant Women Living with HIV Who Are Currently Receiving Antiretroviral Therapy).

Viral load also should be assessed at approximately 34 to 36 weeks gestation to inform decisions about the mode of infant delivery and optimal treatment for newborns (see Intrapartum Care for Women with HIV).

In pregnant women with HIV, CD4 count should be measured at the initial clinic visit (see Table 6 below). For patients who have been on ART for ≥2 years, have had consistent viral suppression and CD4 counts that are consistently >300 cells/mm^3, 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.[6, 11, 12] Women who have been on ART for <2 years, women with CD4 counts of <300 cells/mm^3, and women 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^3 for 1 year) are highly unlikely to experience a CD4 count <350 cells/mm^3 in the span of a year.[13]

HIV drug-resistance testing should be performed in women with HIV before starting or modifying ART if HIV RNA levels are above the threshold for standard resistance testing (i.e., >500 copies/mL to 1,000 copies/mL) (see Table 6 below). Genotypic testing should be performed. In cases of treatment-experienced individuals with multidrug resistance on failing regimens, phenotypic testing should be additionally 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 subsequently adjusted. Antiretroviral (ARV) drug-resistance testing should also be performed on women 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 Women Who Have Not Achieved Viral Suppression on ART 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.

The laboratory tests that are 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 woman is receiving (see Table 6 below). For example, routine hematologic monitoring is recommended for women who are receiving zidovudine-containing regimens, and routine renal monitoring is recommended for women who are receiving tenofovir disoproxil fumarate. Liver function should be monitored in all women 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 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. Hepatic steatosis and lactic acidosis in pregnancy have been related to the use of older nucleoside reverse transcriptase inhibitors, such as stavudine, didanosine, and zidovudine. Pregnant women in general are more likely to have elevated levels of liver enzymes than their nonpregnant counterparts.[14–16]

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%), with women in Asia demonstrating the highest prevalence (7.10%) and those in Africa demonstrating the lowest prevalence (3.19%). These rates do not appear to be higher than those in non-HIV populations.[17,18] The majority of studies in pregnant women have not demonstrated an association between HIV infection and gestational diabetes,[19–23] 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.[24] Two studies reported higher odds of gestational diabetes in women who were receiving PI based regimens,[25,26] but another prospective study reported that pregnant women with HIV who received PI-containing regimens did not have a greater risk for glucose intolerance or insulin resistance than women who received regimens that did not contain a PI.[27] Women 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 women who are receiving PI-based ART that was initiated before pregnancy, in accordance with recommendations for women with risk factors for glucose intolerance, such as obesity (see Table 6 below).[28]

Accurate estimation of date of delivery is critical when planning scheduled cesarean deliveries at 38 weeks gestation to prevent perinatal transmission in women with HIV who have elevated HIV RNA viral loads (or when scheduling cesarean delivery or induction for an obstetric indication).[29] Therefore, it is recommended that health care providers follow the current obstetric guidelines for gestational age dating by ultrasound.[30]

Noninvasive methods of aneuploidy screening should be offered, using tests with high sensitivity and low false-positive rates as recommended by the American College of Obstetricians and Gynecologists. Screening can be accomplished using any of the following:

- Serum analyte screening alone or combined with nuchal translucency;
- Cell-free DNA screening; *or*
- Ultrasonographic screening alone.[31]

Women with HIV who have indications for invasive testing during pregnancy (e.g., abnormal ultrasound or aneuploidy screening) should be counseled about the potential risk of perinatal HIV transmission along with other risks of the procedure so that they can make an informed decision about testing. Although the data on women who are receiving ART are still somewhat limited, the risk of perinatal HIV transmission does not appear to increase with the use of amniocentesis or other invasive diagnostic procedures in women who have virologic suppression on ART.[32,33] This is in contrast to the era before effective ART, during which invasive procedures, such as amniocentesis and chorionic villus sampling (CVS), were associated with a twofold to fourfold increase in the risk of perinatal transmission of HIV.[34–37] Although no transmissions occurred among 159 reported cases of amniocentesis or other invasive diagnostic procedures performed in women who were on effective ART, a small increase in the risk of transmission cannot be ruled out.[38–41] Some experts consider CVS and cordocentesis too risky to offer to women with HIV, and they recommend limiting invasive procedures to

amniocentesis.

At a minimum, pregnant women with HIV should receive effective ART before undergoing any invasive prenatal testing. In addition, they ideally should have undetectable HIV RNA levels at the time of the procedure, and every effort should be made to avoid inserting the needle through, or very close to, the placenta. If a woman with detectable HIV RNA levels requires amniocentesis, consultation with an expert in the management of HIV during pregnancy should be considered (see Intrapartum Care for Women with HIV).

Table 6. HIV-Related Laboratory Monitoring Schedule for Pregnant Women with HIV

	Timepoint or Frequency of Testing						
Laboratory Test	**Entry Into Antenatal Care**	**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 34 to 36 Weeks Gestation to Inform Mode of Delivery and Infant ARV Regimen**
HIV RNA Levels[b]	✓	✓ 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[c]		✓
CD4 Count[d]	✓				✓ For women who have been on ART for <2 years, women with CD4 counts <300 cells/mm^3, and women with inconsistent adherence and/or detectable viral loads		
Resistance Testing[e]		✓					
Standard Glucose Screening[f]						✓ For women on ART[f]	

LFTs for Women on ART		✓			✓ Or as needed		
Monitoring for ARV-Specific Toxicities[g]	Refer to the recommendations in the package inserts for the individual ARV drugs.						

[a]For additional information see Laboratory Monitoring in the Adult and Adolescent Antiretroviral Guidelines

[b] The plasma HIV RNA levels of pregnant women with HIV should be monitored at the initial antenatal visit **(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.

[c] More frequent viral load monitoring (every 1-2 months) may be indicated for women who are taking ARVs that have been shown to have reduced drug levels in the 2nd and 3rd trimesters and are at risk for loss of viral suppression, e.g., cobicistat, elvitegravir or rilpivirine (see Table 4 and Table 5 and Pregnant Women Living with HIV Who Are Currently Receiving Antiretroviral Therapy).

[d] CD4 T lymphocyte (CD4) cell 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^3 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)**. Women who have been on ART for <2 years, women with CD4 counts <300 cells/mm^3, and women with inconsistent adherence and/or detectable viral loads should have CD4 counts monitored every 3 months during pregnancy **(CIII)**.

[e] ARV drug-resistance testing (genotypic testing and, if indicated, phenotypic testing) should be performed in women whose HIV RNA levels are above the threshold for standard resistance testing (i.e., >500 copies/mL to 1,000 copies/mL) before—

- Initiating ART in ARV-naive pregnant women who have not been previously tested for ARV drug resistance **(AII)**;
- Initiating ART in ARV-experienced pregnant women **(AIII)**; *or*
- Modifying ARV regimens for women who become pregnant while receiving ARV drugs or women who have suboptimal virologic response to ARV drugs that were started during pregnancy **(AII)**.

ART should be initiated in pregnant women prior to receiving the results of ARV-resistance tests. ART should be modified, if necessary, based on the results of resistance testing **(BIII)**.

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

[g] 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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