HIV-2 and Pregnancy

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Panel's Recommendations
• HIV-2 infection should be considered in pregnancy when the virus is endemic in the country of origin or the partner's country of origin **(AII).** • When pregnant or trying to conceive with HIV-2 infection, treatment should be based on the guidelines for HIV-1 infection but using antiretroviral (ARV) drugs that are active against HIV-2 **(AIII).** • ARV regimens for use during pregnancy (and when trying to conceive) with HIV-2 mono-infection or HIV-1/HIV-2 coinfection should include an integrase strand transfer inhibitor (INSTI) recommended for use in pregnancy (bictegravir or dolutegravir) plus two nucleoside reverse transcriptase inhibitors (NRTIs) **(AII).** A recommended alternative regimen is ritonavir-boosted darunavir plus two NRTIs **(BII).** See Recommended Antiretroviral Therapy for Treating HIV-2 Infection During Pregnancy below and Recommendations for the Use of Antiretroviral Drugs During Pregnancy: Overview. • During pregnancy (and when trying to conceive) with HIV-2 mono-infection or HIV-1/HIV-2 coinfection, immediate antiretroviral therapy (ART) is recommended **(AII).** • If ART is already being used during pregnancy with drugs that are active against HIV-2, treatment should be continued **(AIII).** • As with HIV-1, the possibility of hepatitis B virus coinfection should be considered when choosing an ARV regimen to treat HIV-2 **(AI)** (see Hepatitis B Virus/HIV Coinfection). • HIV-2 RNA, CD4 T lymphocyte (CD4) cell counts, and clinical status should be monitored for response to treatment **(AII).** In the context of HIV-2, regular CD4 testing should be continued even with below detectable HIV RNA levels (viral load) because disease progression can occur even with undetectable viral load **(AIII).** However, monitoring HIV-2 plasma viral loads in pregnancy and receiving the results in a timely manner can be difficult because plasma samples must be sent to the University of Washington or the New York State Department of Health. • HIV-2 resistance may occur with INSTIs, NRTIs, or protease inhibitors. However, no validated HIV-2 genotypic or phenotypic resistance assays are approved for clinical use. • During pregnancy and when trying to conceive with virologic or immunologic failure, a new ART regimen should be considered in consultation with an HIV expert. For multidrug-resistant virus, ibalizumab and lenacapavir demonstrate *in vitro* activity against HIV-2 but are not recommended except in special circumstances due to insufficient efficacy, pharmacokinetic, and safety data in pregnancy. Shared decision-making should be used when selecting a new ART regimen. • ARV management of infants perinatally exposed to HIV-2 mono-infection or HIV-1/HIV-2 coinfection should follow recommendations for infants perinatally exposed to HIV-1 infection (see Antiretroviral Management of Infants With *In Utero*, Intrapartum, or Breastfeeding Exposure to HIV, Table 11, and Table 12) using drugs that are active against HIV-2 **(AIII)** (see Care of Infants With *In Utero*, Intrapartum, or Breastfeeding Exposure to HIV-2 below). Nevirapine (NVP) should not be used because it lacks activity against HIV-2. • In the context of HIV-2, the same patient-centered, evidence-based counseling should be provided according to the guidance for HIV-1 to support shared decision-making about infant feeding options prior to and during pregnancy; counseling and plans for infant feeding should be reviewed again after delivery **(AIII)** (see Preventing HIV Transmission During Infant Feeding).

- For infants perinatally exposed to HIV-2 infection, ARV prophylaxis during breastfeeding should follow recommendations for infants perinatally exposed to HIV-1 infection (see Antiretroviral Prophylaxis for Breastfeeding Infants in Antiretroviral Management of Infants With *In Utero*, Intrapartum, or Breastfeeding Exposure to HIV, Table 12, and Table 12.1). If extended ARV prophylaxis is used, infants should receive lamivudine since NVP lacks activity against HIV-2 **(CIII).**
- If maternal HIV-2 infection is suspected or confirmed, infant diagnostic testing for HIV-2 can follow the same schedule as for infants perinatally exposed to HIV-1 using virologic assays to diagnose HIV-2 infection. See Diagnosis of HIV Infection in Infants and Children and Table 13. Recommended Virologic Testing Schedules for Infants With Perinatal and Breastfeeding Exposure to HIV for guidance about infant testing.

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*

HIV-2 infection is endemic in West African countries, including Burkina Faso, Cape Verde, The Gambia, Ghana, Guinea, Guinea-Bissau, Ivory Coast, Liberia, Mali, Mauritania, Niger, Nigeria, Sao Tome, Senegal, Sierra Leone, and Togo. HIV-2 is also endemic in Angola, Mozambique, and parts of India.[1]

HIV-2 remains rare in the United States. According to the National HIV Surveillance System, 327,700 diagnoses of HIV were recorded in the United States from 2010 to 2017, of which 198 (0.06%) met the criteria for HIV-2 (HIV-2 mono-infection, n = 102; dual HIV-1 and HIV-2, n = 11; probable but unconfirmed HIV-2, n = 85).[2] Among these cases, 99 women had diagnoses of confirmed or probable HIV-2, and 9 of these women had evidence of pregnancy at or after their diagnosis. No perinatal HIV-2 transmissions were reported. HIV-2 infection should be suspected in pregnancy when the disease is endemic in the country of origin or the partner's country of origin.

Using the currently recommended HIV testing algorithm,[3] people with HIV-2 infection will have positive results on a standard HIV-1/HIV-2 antibody or HIV-1/HIV-2 antigen/antibody immunoassay, which will prompt testing with a supplemental HIV-1/HIV-2 antibody differentiation immunoassay. Individuals with HIV-2 mono-infection will test negative for HIV-1 antibodies and positive for HIV-2 antibodies, whereas both tests will be positive for individuals with HIV-1/HIV-2 coinfection.

The first step in the Centers for Disease Control and Prevention (CDC) HIV testing algorithm is performing an HIV-1/HIV-2 antigen/antibody combination assay on serum or plasma (e.g., Abbott Architect HIV Ag/Ab combo assay, Bio-Rad GS Combo Ag/Ab EIA, Alere Determine).[3,4] This test does not distinguish between HIV-1 antibodies and HIV-2 antibodies. Specimens that are reactive on this test must be tested with a U.S. Food and Drug Administration (FDA)–approved antibody assay to distinguish HIV-1 antibodies from HIV-2 antibodies. The FDA-approved HIV-2 antibody supplemental test Geenius (Bio-Rad Laboratories) is used as part of the CDC-recommended HIV laboratory testing algorithm.

Viral load assays for HIV-2 are not commercially available, but they may be available under research protocols. The University of Washington[5] and the New York State Department of Health Wadsworth Center[6] also offer HIV-2 viral load assays. The University of Washington accepts specimens forwarded from laboratories, such as Quest Diagnostics. All HIV-2 cases should be reported to the HIV surveillance program of the state or local health department, which can arrange for additional confirmatory testing for HIV-2 by the CDC.[7] No validated HIV-2 genotype or phenotype resistance assays are available in the United States. HIV-2 genotypic resistance assays are available for research use only at the University of Washington. Drug resistance against HIV-2 can be determined using the HIV-2 EU resistance tool and a French resistance tool.[8,9]

HIV-2 has a longer asymptomatic phase than HIV-1, with a slower progression to AIDS. However, without effective antiretroviral therapy (ART), HIV-2 will progress to AIDS and death in the majority of individuals over time.[10] The most common mode of HIV-2 transmission is through sex. HIV-2 infection does not protect against HIV-1, and dual infection—which carries the same prognosis as HIV-1 mono-infection—can occur.[11] HIV-2 is less infectious than HIV-1, with a fivefold lower rate of sexual transmission and a 20-fold to 30-fold lower rate of perinatal transmission.[12-14]

Several studies confirm that rates of HIV-2 perinatal transmission are low with and without interventions (0% to 4%), which may be a result of reduced plasma viral loads, higher CD4 T lymphocyte (CD4) cell counts, and less cervical viral shedding in women with HIV-2 infection than in women with HIV-1 infection. In a systematic review and meta-analysis comparing perinatal transmission of HIV-1 and HIV-2, the pooled incidence of HIV-2 perinatal transmission was 0.2% (95% confidence interval [CI], 0.03% to 1.47%) among antiretroviral-naive pregnant women.[15] The review found that the perinatal transmission rate of HIV-2 is influenced by higher viral load and lower CD4 count of the mother. In general, mothers with HIV-2 had lower viral loads and higher CD4 counts than those with HIV-1. HIV-2 can also be transmitted through breastfeeding.[16]

Recommended Antiretroviral Therapy for Treating HIV-2 Infection During Pregnancy

Pregnancy with HIV-2 infection should be treated according to the guidelines for HIV-1 mono-infection, although clinicians should make sure that the chosen antiretroviral (ARV) regimen is also appropriate for treatment of HIV-2. Once treatment is started, ART should be continued postpartum as is recommended for HIV-1. The integrase strand transfer inhibitors (INSTIs) raltegravir (RAL), elvitegravir, dolutegravir (DTG), bictegravir (BIC), and cabotegravir (CAB) are effective against HIV-2.[17,18] HIV-2 has variable susceptibility to protease inhibitors (PIs), with lopinavir (LPV) and darunavir having the most activity.

Pregnancy care with HIV-2 infection alone has been based on expert opinion and extrapolation from both HIV-1 treatment and treatment of HIV-2 in nonpregnant adults.[19] An ART regimen containing two nucleoside reverse transcriptase inhibitors (NRTIs) and a *Preferred* INSTI (i.e., DTG or BIC) is currently recommended for use in pregnancy; a regimen of two NRTIs and ritonavir-boosted darunavir (DRV/r) is recommended as an *Alternative*. See Recommendations for the Use of Antiretroviral Drugs During Pregnancy: Overview, Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy When Antiretroviral Therapy Has Never Been Received, Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs During Pregnancy and When Trying to Conceive, and Appendix C: Antiretroviral Counseling Guide for Health Care Providers.

The following regimens can be used to treat HIV-2, based on the available efficacy and safety data on the use of these drugs during pregnancy from clinical trials in the setting of HIV-1 infection:

- BIC or DTG (with two NRTIs) are *Preferred* regimens for HIV-2 when pregnant or trying to conceive as well as in the context of HIV-1. RAL (with two NRTIs) is an *Alternative* INSTI regimen for treating HIV-2 as well as HIV-1. See Table 6 and Table 7.
- DRV/r (with two NRTIs) is an *Alternative*, PI-based regimen in the context of HIV-2 when pregnant or trying to conceive as well as in the context of HIV-1. Ritonavir-boosted lopinavir (with two NRTIs) is active against HIV-2 and can be used in special circumstances for treating HIV-2 as well as HIV-1. See Table 6 and Table 7.
- *Preferred* NRTIs recommended as part of a full ART regimen for HIV-2 when pregnant or trying to conceive are the same as those recommended for treatment of HIV-1 during pregnancy: tenofovir disoproxil fumarate or tenofovir alafenamide plus emtricitabine (FTC) or lamivudine (3TC). Abacavir (ABC) plus 3TC or FTC is an *Alternative* NRTI backbone for use during

pregnancy or when trying to conceive. See Table 6 and Table 7 for considerations on the use of ABC. Zidovudine (ZDV) plus 3TC can be used as an *Alternative* dual-NRTI backbone.

- If ART is already being used during pregnancy with drugs that are active against HIV-2, treatment should be continued.
- ART regimens containing non-nucleoside reverse transcriptase inhibitors (including long-acting injectable rilpivirine given with the INSTI CAB), enfuvirtide, and fostemsavir are not recommended and **should not be used** because they are not active against HIV-2 (see HIV-2 Infection in the Adults and Adolescent Antiretroviral Guidelines).

Although DTG may be able to rescue a failing RAL-based regimen in a person with HIV-2 infection, a study has reported the emergence of DTG-resistance mutations in people with HIV-2 infection.[20] The CCR5 antagonist maraviroc appears to be active against some strains of HIV-2, although no approved assays exist to determine HIV-2 co-receptor tropism.[21,22] HIV-2 drug resistance has been documented with various ARV drugs.[23,24] Among 47 ART-naive people with HIV-2, ultradeep sequencing showed that three people displayed plasma viruses with a resistance-associated mutation (RAM) above the 20% detection threshold, with a prevalence of transmitted drug resistance for NRTIs of 7.9% (95% CI, 0.0% to 16.5%). No RAM above the 20% detection threshold was found for PIs or INSTIs.[25] For multidrug-resistant virus, ibalizumab[26] and Lenacapavir[27] demonstrate *in vitro* potency against HIV-2 and may be considered; these drugs are not recommended except in special circumstances for use in pregnancy.

When monitoring the plasma viral loads and CD4 counts during pregnancy with HIV-2 infection, clinicians should follow the guidelines outlined for HIV-1 infection (see Initial Evaluation and Continued Monitoring of HIV During Pregnancy). However, disease progression can occur in the setting of undetectable HIV-2 plasma viral load. When HIV-2 plasma viral loads are below the limits of detection, routine CD4 counts and clinical monitoring should still be performed (see Plasma HIV-1 RNA [Viral Load] and CD4 Count Monitoring in the Adult and Adolescent Antiretroviral Guidelines).

No data exist on the impact of scheduled cesarean delivery on HIV-2 perinatal transmission. No evidence supports a recommendation to schedule cesarean delivery for the purpose of reducing HIV-2 perinatal transmission. In addition, data are not available to address whether treatment should be continued after pregnancy with HIV-2 mono-infection. To date, no randomized trials have addressed the question of an optimal treatment strategy for HIV-2 infection. The Adult and Adolescent Antiretroviral Guidelines recommend that all HIV-2 infection should be treated using the guidelines provided for HIV-1 infection (see HIV-2 Infection).

Care of Infants With *In Utero*, Intrapartum, and Breastfeeding Exposure to HIV-2

As noted above, rates of perinatal (*in utero* and intrapartum) transmission of HIV-2 are low with and without interventions, and it is unclear whether infants perinatally exposed to undetectable HIV-2 viral loads will benefit from ARV prophylaxis.[19] However, monitoring HIV-2 plasma viral loads in pregnancy and receiving the results in a timely manner can be difficult because plasma samples must be sent to the University of Washington or the New York State Department of Health. Therefore, the Panel on Treatment of HIV in Pregnancy and Prevention of Perinatal Transmission (the Panel) recommends that all infants perinatally exposed to HIV-2 mono-infection or HIV-1/HIV-2 coinfection receive ARV prophylaxis following recommendations for infants perinatally exposed to HIV-1 infection (see Antiretroviral Management of Infants With *In Utero*, Intrapartum, or Breastfeeding Exposure to HIV, Table 11, and Table 12) using drugs that are active against HIV-2 as summarized below. The Panel recognizes that data about *in utero* and intrapartum transmission risk according to maternal HIV-2 RNA levels and receipt of infant ARV prophylaxis are limited, and there may be fewer viral load test results in instances of HIV-2 mono-infection during pregnancy than

for HIV-1 during pregnancy. Therefore, maternal receipt of and adherence to an ART regimen that is active against HIV-2 and the lower risk of perinatal transmission of HIV-2 infection are factors to consider when making decisions about the use of ZDV prophylaxis alone or a three-drug presumptive HIV therapy regimen for infants perinatally exposed to HIV-2 mono-infection.

- Infants at low risk of *in utero* and intrapartum HIV acquisition, defined as perinatal exposure to HIV-2 (and HIV-1) RNA levels <50 copies/mL from 20 weeks of gestation through delivery, should receive ZDV alone for 2 weeks.
- Infants at high risk of HIV infection from *in utero* or intrapartum exposure, defined as perinatal exposure to viremia (HIV-2 and/or HIV-1 RNA levels ≥50 copies/mL) in the 4 weeks prior to delivery, should be provided a three-drug ARV regimen administered from birth for 2 weeks to 6 weeks that serves as presumptive HIV therapy or enhanced prophylaxis. Infants with exposure to HIV-2 should receive a regimen of RAL plus ZDV plus 3TC; nevirapine (NVP) should not be used because it lacks activity against HIV-2. If the duration of the three-drug regimen is shorter than 6 weeks, ZDV should be continued alone to complete a total of 6 weeks of prophylaxis.
- Infants not meeting criteria for high or low risk should receive ARV regimens and durations based on case-specific factors related to the level and timing of viremia during the pregnancy (i.e., 2 to 6 weeks of ZDV prophylaxis **or** a three-ARV presumptive HIV therapy regimen of ZDV plus 3TC plus RAL). See Table 11 in Antiretroviral Management of Infants With *In Utero*, Intrapartum, or Breastfeeding Exposure to HIV. Examples of case-specific factors can include viremia in the first 20 weeks of pregnancy, diagnosis of HIV at delivery or immediately postpartum, etc.

In the context of HIV, patient-centered, evidence-based counseling should be provided during all pregnancies to support shared decision-making about infant feeding. The risk of infant HIV-2 infection from breastfeeding is lower for HIV-2 than for HIV-1, but the risk is not zero.[16] Counseling about infant feeding should begin prior to conception or as early as possible in pregnancy; information about and plans for infant feeding should be reviewed throughout pregnancy and again after delivery (see Preventing HIV Transmission During Infant Feeding). For infants perinatally exposed to HIV-2 infection, ARV prophylaxis during breastfeeding should follow recommendations for infants perinatally exposed to HIV-1 infection (see Antiretroviral Prophylaxis for Breastfeeding Infants in Antiretroviral Management of Infants With *In Utero*, Intrapartum, or Breastfeeding Exposure to HIV, Table 12, and Table 12.1). If extended ARV prophylaxis is used, infants should receive 3TC since NVP lacks activity against HIV-2.

Infants born to mothers with HIV-2 should be tested for HIV-2 infection with HIV-2-specific virologic assays at the same time points as those used for HIV-1 testing; see Diagnosis of HIV Infection in Infants and Children and Table 13. Recommended Virologic Testing Schedules for Infants With Perinatal and Breastfeeding Exposure to HIV.[28] Quantitative HIV-2 plasma RNA viral load testing for clinical care is available from the University of Washington[5] and the New York State Department of Health.[6] Antibody testing of infants (e.g., with the Bio-Rad Laboratories Multispot HIV-1/HIV-2 test) can also be performed after age 18 months to confirm clearance of HIV-2 antibodies if infant HIV-2 nucleic acid testing has been incomplete.

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