Women With HIV

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Panel's Recommendations
Antiretroviral Therapy for Women With HIV
• ART is recommended for all people with HIV to improve their health and to reduce the risk of HIV transmission to sexual partners without HIV **(AI).**
• A pregnancy test should be performed for women of reproductive potential before initiation of ART **(AIII).** Clinicians should discuss intentions regarding pregnancy with all women of reproductive potential.
• When selecting or evaluating an ARV regimen for women who are considering pregnancy, clinicians should consider the regimen's effectiveness, the woman's hepatitis B status, the teratogenic potential of the drugs in the ARV regimen, and the possible adverse outcomes for the mother and the fetus if the woman becomes pregnant while receiving the regimen **(AII).**
• Drug interactions between ART and hormonal contraceptives and hormone replacement therapy are less of a concern with second-generation INSTI-based regimens than some other ARV drugs. When prescribing ARV regimens for women with HIV, clinicians should consider the potential for PK interactions between ARV drugs and with hormonal contraceptives **(AII)** and hormone replacement therapy. Refer to the Liverpool HIV Drug Interaction Checker for a summary of available data and recommendations when selecting ARV and hormone combination therapy.
• Weight gain after initiation of ART occurs in most patients. Some studies suggest increased weight gain in women, particularly among Black women. ART initiation or switch should not be delayed due to concern for weight gain, and shared decision-making should inform ARV choices.
Antiretroviral Therapy During Pregnancy
• All women with HIV should initiate ART before or early in pregnancy for their own health and for the prevention of perinatal HIV transmission and transmission of HIV to sexual partners **(AI).**
• During pregnancy, an additional goal of ART is to maintain a viral load below the limit of detection throughout pregnancy to reduce the risk of HIV transmission to the fetus and newborn **(AI).**
• When selecting an ARV regimen for a pregnant woman, clinicians should consider the available safety, efficacy, and PK data of each agent during pregnancy. The benefits and risks of specific ARV regimens during pregnancy should be discussed with all pregnant women **(AIII),** and clinicians should consult the Perinatal Guidelines when designing a regimen**.**
Antiretroviral Therapy Postpartum
• ART should be continued postpartum **(AI).**
• Counseling on infant feeding options should be provided to all postpartum women.
• Clinicians should support maternal ART adherence for women with HIV and viral suppression (<50 copies/mL for at least 3 months) who choose to breastfeed (see Adherence to the Continuum of Care).
• Breastfeeding **is not recommended** for women who are not virally suppressed or for those who develop a detectable viral load (≥50 copies/mL) while breastfeeding. See the Perinatal Guidelines for detailed recommendations.
Special Considerations for Menopause and Comorbidities
• Preferred ARV regimens are the same for menopausal women with HIV as for other populations **(AIII).**
• Counseling and consideration of menopausal symptoms and comorbidities common among women in menopause—including cardiovascular disease, weight gain, neurocognitive decline, bone loss, and depression—should be a part of comprehensive HIV care.

Rating of Recommendations: *A = Strong; B = Moderate; C = Weak*

Rating of Evidence: *I = Data from randomized controlled trials; II = Data from well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion*

Key: ART = antiretroviral therapy; ARV = antiretroviral; INSTI = integrase strand transfer inhibitor; PK = pharmacokinetic

Introduction

This section outlines key clinical and therapeutic considerations and basic principles related to antiretroviral (ARV) drug use in women with HIV. Clinicians should consult the Perinatal Guidelines for a more in-depth discussion regarding preconception counseling and care during pregnancy and in the postpartum period. Historically, women have represented the minority of participants in registrational trials of antiretroviral therapy (ART) and in studies of specific regimens and their associations with comorbid conditions.[1] Where available, evidence for differences between men and women from comparative trials or observational cohort data for efficacy and safety from trials done in women and specific risks or therapeutic considerations in women across the reproductive lifespan are discussed in this section.

Antiretroviral Therapy Considerations

In Women of Reproductive Potential

All women with HIV who are of reproductive potential should be offered comprehensive reproductive and sexual health counseling and care as part of routine primary medical care. Topics for discussion should include safe sex practices, reproductive desires and options for conception, the HIV status of sexual partner(s), the use of effective contraception to prevent unplanned pregnancy, and the importance of ART in maintaining viral suppression to optimize health in preparation for pregnancy. Counseling also should include discussion of special considerations pertaining to ARV use when using hormonal contraceptives, when trying to conceive, and during pregnancy (see the Perinatal Guidelines). Clinicians should regularly discuss intentions regarding pregnancy with all women of reproductive potential. A pregnancy test should be performed before initiating ART **(AIII).**

Before initiating ART in a woman of reproductive potential, clinicians should review the What to Start: Initial Combination Antiretroviral Regimens for People With HIV section and the Perinatal Guidelines for information to consider when choosing an ARV regimen. For information on the safety and efficacy of different ARV drugs during pregnancy, please review the Perinatal Guidelines.

For women with HIV who are planning to conceive, ART should be initiated and viral suppression achieved before pregnancy whenever possible. Women with HIV should be given information about the benefits and risks of initiating specific ARV regimens when trying to conceive so they can make informed decisions about their care (see the Antiretroviral Counseling Guide for Health Care Providers in the Perinatal Guidelines).

For women with HIV who are not planning to conceive, but who may become pregnant, please see *Recommended Initial Regimens for Most People With HIV* and *Initial Antiretroviral Regimens for Certain Clinical Scenarios*. Clinicians should also refer to the Perinatal Guidelines for recommendations.

For women with HIV who are pregnant, please review the Pregnancy section below and the Perinatal Guidelines for more detailed discussion about ART use during pregnancy and postpartum.

In Women Who Are Not of Reproductive Potential

Some women with HIV do not have the potential to conceive because of medical, surgical, or other factors (e.g., they do not have a uterus, ovaries, or fallopian tubes or because they are postmenopausal). Recommendations for ART are the same as for other people with HIV (see What to Start, Optimizing Antiretroviral Therapy in the Setting of Viral Suppression, and Virologic Failure). However, there are still some important sex differences to consider, as described below.

Sex Differences in Antiretroviral Therapy

In general, studies to date have not shown sex differences in virologic responses to ART.[2-7] However, limited data show that pharmacokinetics (PK) of some ARV drugs may differ between men and women, possibly due to variations in factors such as body weight, plasma volume, gastric emptying time, plasma protein levels, cytochrome P450 activity, drug transporter function, and excretion activity.[7-11]

Adverse Effects

In general, currently available ART regimens are efficacious in both men and women. There is uncertainty about the specific risks of adverse effects in women due to lack of sufficient data.[12]

Several studies with older ARV drugs have suggested that sex may influence the frequency, presentation, and severity of some ARV-related adverse events.[13-15] Sex differences in adverse effects–related discontinuation rates of integrase strand transfer inhibitors (INSTIs) have also been reported.[16] In the ICONA cohort, ART-naive and ART-experienced women with HIV treated with dolutegravir (DTG)-based regimens had a higher risk of toxicity-related discontinuation compared with men through up to 4 years of follow-up.[17] A subsequent systematic review and meta-analysis of 15 observational DTG studies that included 7,506 women reported higher odds of DTG discontinuation due to side effects in women than in men; however, no sex differences in neuropsychiatric side effect–related discontinuations were observed.[16] It is unclear whether this difference is a class effect, because an older study reported higher discontinuation rates of non-INSTI-based regimens in women compared to historical studies in men.[18]

Women have an increased risk of osteopenia, osteoporosis, and fractures, particularly after menopause, and this risk is exacerbated by HIV and some ARV drugs.[19-22] ARV regimens that contain tenofovir disoproxil fumarate (TDF), boosted protease inhibitors, or both are associated with a significantly greater loss of bone mineral density (BMD) than regimens that contain other nucleoside reverse transcriptase inhibitors or raltegravir (RAL).[23-26] Clinicians should consider avoiding TDF if possible in women with HIV who have high risk for osteoporosis and fracture. Recommendations for the management of bone disease in people with HIV have been published.[27]

Weight Gain and Antiretroviral Therapy

Weight gain is common after initiating ART, and decisions regarding ART regimens should be centered on optimization of viral suppression (see Weight Gain in People With Treated HIV). Selection of ART regimens either for initiation or switch should not be guided by whether a particular medication will prevent or decrease weight gain. The mechanisms underlying differences in ART-associated weight gain remain unclear, including differences with particular regimens and differences by sex. Clinicians should have informed discussions with people with HIV, especially women, regarding the potential for weight gain with ART initiation or switch as part of shared decision-making. Counseling weight management strategies should be a part of comprehensive HIV care. Data from clinical trials and longitudinal cohort studies suggest sex differences in ARV-associated weight gain across all classes of ART among treatment-naive individuals, particularly with the use of certain INSTI-based regimens (DTG and bictegravir). In a pooled analysis of eight

randomized controlled trials with ARV-naive people initiating ART, female sex was associated with approximately 50% higher odds of a ≥10% weight gain compared with male sex (17.4% vs. 12.2%), with Black females being significantly more likely to experience a ≥10% weight gain than non-Black females (19.7% vs. 12.4%).[28] At 144 weeks of follow-up in the ADVANCE study, a 12.3-kg weight gain was recorded among women receiving tenofovir alafenamide (TAF)/emtricitabine (FTC)/DTG compared with 7.4 kg and 5.5 kg among women receiving TDF/FTC/DTG and TDF/FTC/efavirenz (EFV), respectively.[29] In addition to women being more likely to experience weight gain with ARV initiation, the pattern of weight gain differs between men and women. In the ADVANCE study, at 96 weeks of follow-up, women gained more fat than lean body mass when compared to men, with weight gain concentrated in the limbs and trunk. ARV-associated weight gain similarly has been observed among virologically suppressed women switching to an INSTI-based regimen.[30-32] In the Women's Interagency HIV Study (WIHS), virologically suppressed women who switched to INSTI-based ART or had an INSTI added to their regimen (n = 234) gained an average of 4.2 kg in body weight at the 2-year follow-up compared with 0.2 kg in women remaining on non-INSTI ART (n = 884).[31] Mean change in percent body fat (1.7% vs. 0.3%) and body circumference measures were also greater in the INSTI group than in the non-INSTI group. Investigators did not detect a difference in weight gain by individual INSTI. In an observational study of women with HIV and viral suppression, 419 women who switched to an INSTI-based regimen (47% switched to second-generation INSTIs) were compared to 712 women who did not switch. There was a significantly faster increase in waist circumference per 6 months in the INSTI group compared to the non-INSTI group when the switch occurred in late perimenopause and menopause. This difference was not observed in the premenopausal participants. Although there were significantly higher proportions of participants on TDF and EFV in the non-INSTI group, the finding of increases in waist circumference in the INSTI group remained in sensitivity analyses restricted to participants on TDF and when participants on EFV were excluded.[33]

Switching from TDF to TAF, regardless of whether participants took INSTI, non-nucleoside reverse transcriptase inhibitor (NNRTI), or PI combinations, was found to be associated with weight gain, particularly in women and people of African descent.[34] The extent of TAF-associated weight gain may be affected by baseline body mass index (BMI). Among participants of the WIHS cohort, weight and BMI rose among women with baseline BMI <30 kg/m^2 when transitioning to INSTI, TAF, or INSTI and TAF together.[35]

It should be noted that, although randomized controlled trials and observational studies suggest that individuals receiving INSTI-based regimens experience greater weight gain than those receiving comparator regimens, substantial uncertainty continues as to whether INSTIs are causing weight gain or whether the comparator drugs are suppressing weight gain.[36] The underlying mechanisms for weight gain in people receiving an INSTI-based regimen, and their impact on cardiovascular diseases, diabetes, pregnancy-related outcomes, and age-related comorbidities among women with HIV are currently unknown.

Adherence to Antiretroviral Therapy

Several U.S. studies have demonstrated lower rates of ART adherence among women compared with men. CDC data from the Medical Monitoring Project show that only about 60% of women reported perfect adherence over the prior 30 days between 2015 and 2019.[37] Large observational studies using Medicare claims and commercial databases similarly found that women had higher odds of nonadherence than men, whether measured by percent days covered or short-term dose recall.[38,39] A Canadian cohort showed that women were significantly less likely than men to maintain optimal adherence, even after adjusting for factors such as ethnicity and injection drug use.[40]

Multiple barriers contribute to adherence challenges in women with HIV. Women with low adherence are more likely to experience depression, alcohol use, and unmet social needs.[41] Access to food, housing, transportation, social support, and strong patient–provider relationships have been linked to

better adherence.[42-44] Structural factors including poverty, transportation challenges, limited health literacy, and gaps in insurance coverage also explain part of the racial disparities in adherence among women.[45] Age plays a role as well: Women aged 50 and older tend to have better adherence than younger women,[36] yet menopausal symptoms are common and are associated with poorer adherence.[37,38] Despite nearly 70% of older women reporting menopausal symptoms, only a small proportion receive treatment for these symptoms. It is possible that addressing these symptoms may help improve adherence to ART.[38,39]

Reproductive Options for Couples With Differing HIV Status

Couples with differing HIV status should be informed of options to prevent sexual transmission of HIV while attempting conception. If the partner with HIV is on ART and has achieved sustained viral suppression, sexual intercourse without a condom allows conception with effectively no risk of sexual HIV transmission to the partner without HIV (see Antiretroviral Therapy to Prevent Sexual Transmission of HIV).[46-48] People with HIV who intend to prevent transmission by using ART need to maintain high levels of ART adherence and should be informed that transmission is possible during periods of poor adherence or treatment interruption, which may lead to viremia. The addition of pre-exposure prophylaxis for the partner without HIV in such situations will further reduce the risk of HIV transmission. Both partners should be screened for sexually transmitted infections (STIs) and receive appropriate treatment if STIs are diagnosed.

Considerations for Women of Reproductive Potential Who Are Not Planning to Conceive

Hormonal Contraception

Safe and effective reproductive health and family planning services to prevent unplanned pregnancies and perinatal transmission of HIV are essential components of care for women with HIV of reproductive potential. These women should receive ongoing counseling on reproductive issues. Individuals who do not desire pregnancy currently but are sexually active or considering initiating sexual activity should be offered effective and appropriate contraceptive methods to reduce the likelihood of unintended pregnancy. Women with HIV can use all available contraceptive methods (e.g., pill, patch, ring, injection, implant) and intrauterine devices (IUDs),[49] after consideration of potential drug–drug interactions (DDIs) as discussed below (also see the Perinatal Guidelines).

Drug–Drug Interactions Between Hormonal Contraceptives and Antiretroviral Drugs

The widespread use of second-generation INSTI-based regimens has decreased the potential for clinically significant DDIs with hormonal contraceptives. However, interactions that may reduce contraceptive efficacy remain a concern with select nonpreferred ARV drugs. Predicting the clinical implications of these interactions is challenging, as most data are from short-duration PK studies in healthy volunteers, and clinical data in women with HIV are limited. The magnitude of change in drug concentrations that may reduce contraceptive efficacy or increase adverse effects is also not known for all forms of contraceptive.

When prescribing ARV regimens for women with HIV, clinicians should consider the potential for PK interactions between ARV drugs and with hormonal contraceptives **(AII).** Concerns about PK interactions should not prevent clinicians from prescribing hormonal contraceptives for individuals on ART. However, an alternative or additional effective contraceptive method is recommended if significant interactions may occur between the chosen hormonal contraceptive and select ARV regimens, particularly those containing EFV, cobicistat (COBI), or ritonavir (RTV). When appropriate, the interacting ARV drug may be switched to an effective alternative with lower interaction potential

based on ARV history and prior resistance testing results (see Optimizing Antiretroviral Therapy in the Setting of Viral Suppression). A summary of key contraceptive interactions with select ARVs is listed below and also in Drug Interactions Between Antiretroviral Agents and Hormonal Contraceptives in the Perinatal Guidelines. Clinicians are encouraged to check for DDIs by using the Liverpool HIV Drug Interaction Checker.

Cobicistat- and Ritonavir-Containing Regimens: These pharmacokinetic boosters present a complex interaction profile. The concomitant use of COBI- or RTV-containing regimens with drospirenone-containing contraceptives should be avoided due to the increased risk of hyperkalemia.[50] While these PK boosters can decrease estrogen levels (potentially causing spotting), they tend to increase progestin exposure, which generally preserves contraceptive effectiveness.[51,52] The increase in progestin exposure does not necessitate a dosage adjustment; however, women with HIV using these combinations should be monitored for progestin-related adverse effects.

Efavirenz: EFV significantly decreases the concentration of progestins delivered by most hormonal methods, including combined oral contraceptives, vaginal rings, progestin-only pills, and contraceptive implants.[51,52] This reduction creates a risk of contraceptive failure, and these methods are generally not recommended for use with EFV-based regimens. Injectable depot-medroxyprogesterone acetate (DMPA) is a notable exception, as a significant reduction in medroxyprogesterone acetate exposure has not been described with EFV. No change in DMPA dose or frequency is necessary.

Hormonal Contraceptives Considerations in Adolescents

In adolescents, there may be concerns about the impact of long-term DMPA use on bone health with or without coadministration of ART, specifically TDF. These concerns should not preclude the use of DMPA as an effective contraceptive unless clinical evidence indicates bone fragility. Refer to Special Considerations for Antiretroviral Therapy Use in Adolescents With HIV in the Pediatric Guidelines for more information.[51-57]

Pregnancy

All women with HIV should initiate ART before or early in pregnancy for their own health and for the prevention of perinatal HIV transmission and transmission of HIV to sexual partners **(AI).** Effective ART reduces the risk of perinatal HIV transmission by decreasing maternal viral load in blood and genital secretions.[58-60] Clinicians who are caring for pregnant adults and adolescents with HIV should review the Perinatal Guidelines for more detailed discussions.

Antiretroviral Regimen Considerations

In general, the recommendations for the use of ART in pregnant women are the same as those for women who are not pregnant. As in nonpregnant individuals, genotypic drug-resistance testing is recommended for all pregnant women before initiating ARV drugs **(AIII)** and for those with detectable HIV viral load while on ART **(AI).** However, if not yet on ART, ART initiation should not be delayed pending genotypic drug-resistance test results. The ARV regimen can be modified, if necessary, once the resistance test results are available **(AIII).** Unique considerations that influence recommendations on the ARV drugs to use during pregnancy include the following:

- Potential ARV-associated adverse effects for pregnant women, fetuses, and infants
- Need for strict adherence to the prescribed ARV regimen to avoid viremia and drug resistance, optimize health outcomes, and minimize the risk of perinatal transmission
- Limited long-term outcome data for infants who were exposed to ARV drugs *in utero*, especially for newer ARV drugs

Clinicians should review the Perinatal Guidelines for ARV drug recommendations for individuals who recently have received an HIV diagnosis or those who become pregnant while on ART. Selection of ARV drugs for pregnant women should be individualized according to specific ARV history, the results of drug-resistance assays, and the presence of comorbidities, including hepatitis B coinfection, as well as the individual's preferences for balancing known and unknown risks and benefits of an ARV regimen.

Because of data suggesting decreased drug levels during pregnancy and associated loss of viral suppression, COBI-containing regimens, including those with atazanavir, EVG, or DRV, **are not recommended** for initiation during pregnancy **(AII).**[61] A pregnant woman who has a suppressed plasma viral load on one of these regimens could continue the regimen with frequent (e.g., monthly) viral load monitoring **(BIII).** Alternatively, another regimen that is expected to maintain viral suppression can be used for the duration of the pregnancy.

Because evidence on the safety, efficacy, and pregnancy outcomes of long-acting injectable cabotegravir and rilpivirine (LA CAB/RPV) during pregnancy remains insufficient, no recommendation can be made for or against its use at this time. Data from case reports and PK modeling studies of women who became pregnant while receiving LA CAB/RPV suggest that monthly LA CAB/RPV dosing maintains CAB concentrations required for antiviral efficacy, but every-2-month dosing requires further study.[62-64] RPV dosed monthly and every 2 months may not maintain adequate levels for antiviral efficacy. In some reports, viral suppression was maintained in women who continued LA CAB/RPV during pregnancy, and no fetal adverse effects were observed.[62-66] For women already maintained on LA CAB/RPV at the start of pregnancy, counseling regarding the limited data of this regimen should be provided. Shared decision-making should inform these discussions and decisions regarding ART regimens. Options include switching to one of the recommended oral regimens during pregnancy or continuation of LA CAB/RPV with close viral load monitoring (every 1–2 months). In women with HIV who have barriers to oral ART and who are taking LA CAB/RPV and have viral suppression at the start of pregnancy and maintained during pregnancy, continuation of monthly LA CAB/RPV or switching from every-2-month to monthly dosing during pregnancy can be considered (see the Perinatal Guidelines).

To reduce the risk of perinatal HIV transmission, intravenous zidovudine during labor is recommended for pregnant women with HIV RNA that is unknown or ≥1,000 copies/mL near delivery, or those with known or suspected lack of adherence since the last HIV RNA result, regardless of the mode of infant delivery **(AI).** Administration of combination ART should continue during labor and before a cesarean delivery (oral medications can be administered with sips of water during this time).

Clinicians who are treating pregnant women with HIV are strongly encouraged to report cases of prenatal exposure to ARV drugs to the Antiretroviral Pregnancy Registry.

Postpartum Management

Following delivery, clinical, immunologic, and virologic follow-up should continue as recommended for nonpregnant adults and adolescents. Maternal ART should be continued after delivery **(AI).** For more information regarding postpartum management of HIV, refer to the Perinatal Guidelines.

Some studies have demonstrated that adherence to ART may decline during the postpartum period.[67-69] Clinicians should address ART adherence at each postpartum clinic visit, including an evaluation of specific factors that facilitate adherence or present as a barrier to adherence. Clinicians may recommend an intervention to improve adherence (see Adherence to the Continuum of Care).

Clinicians should discuss future reproductive plans and timing, the risks and benefits of conceiving on specific ARV medications, and the use of appropriate contraceptive options to prevent

unintended pregnancy. If a long-acting (LA) reversible contraceptive—such as an implant or IUD—is desired, it should be inserted before hospital discharge or during the postpartum visit if possible.

Infant Feeding

Clinicians should refer to the Perinatal Guidelines for detailed recommendations regarding initiation or modification of infant feeding. Women with HIV should receive evidence-based, patient-centered counseling to support shared decision-making about their desired approach to infant feeding. Replacement feeding with properly prepared formula or pasteurized donor human milk eliminates the risk of postnatal HIV transmission to the infant. Clinicians should support maternal ART adherence for women with HIV and viral suppression (<50 copies/mL for ≥3 months) who choose to breastfeed. Refer to the Perinatal Guidelines for additional considerations to minimize risk of transmission.

Breastfeeding is **not recommended** for women who are not virally suppressed or for women who develop a detectable viral load while breastfeeding because of concern for increased risk of HIV transmission through breast milk **(AI).**[70] If viremia occurs during breastfeeding, the woman should be advised to replace breastfeeding with another mode of feeding. Viral load testing should be repeated and plasma genotypic resistance testing should be performed if the level of viremia allows for a test to be done.

HIV and Menopause

The population of people with HIV is aging; thus, the number of women with HIV who are experiencing menopause is increasing. The median age of menopause in the general U.S. population is 52.5 years.[71] Evidence suggests that women with HIV are reaching menopause at earlier ages than women who do not have HIV.[72,73] The WIHS cohort, which included 3,059 participants, demonstrated that approximately 1% (n = 35) experienced premature menopause before age 41, 3% (n = 101) between ages 41 and 45, and 21% (n = 442) between ages 46 and 50. These participants self-reported low use of hormone replacement therapy (HRT), with rates of 14%, 16%, and 7%, respectively.[74]

A Canadian study of 229 women with HIV reported that the average age of menopause was 48 years, which was 3 years younger than the general Canadian population. Lower level of education and hepatitis C virus (HCV) coinfection were associated independently with menopause at <45 years of age.[75] In another study of 667 women with HIV in Rio de Janeiro, Brazil, 24% reached menopause during the observational period and 27% had early menopause (<45 years of age). The median age of menopause was 48 years of age. Age at menarche <11 years, cigarette smoking, chronic HCV, and CD4 T lymphocyte (CD4) count <50 cell/mm^3 were significantly associated with an earlier age of natural menopause.[76]

In general, the recommendations for the use of ART in menopausal women are the same as for other populations. Menopause is a high-risk period for osteoporosis, which may be exacerbated by HIV and/or ART. A small, randomized international multicenter study demonstrated a trend of increased BMD at the lumbar spine after a switch from TDF to TAF in peri- and early postmenopausal women with HIV.[77] HIV confers a larger increase in relative risk of atherosclerotic cardiovascular disease (ASCVD), including incident myocardial infarction in women as compared to the impact of HIV on ASCVD risk in men.[78-80] In addition, ASCVD risk scores underpredict risk for cardiovascular events in people with HIV, with greater underprediction observed among women than men.[81] Because increased age and menopause are both risk enhancers for cardiovascular disease (CVD), this period is a critical time for CVD risk prevention strategies. Prevention strategies may include avoidance of ART regimens associated with increased cardiovascular risk (e.g., abacavir) and initiation of statin therapy. Attention should also be given to diabetes prevention;

faster increases in insulin resistance have been demonstrated in perimenopausal and postmenopausal women with HIV than women without HIV, regardless of ART regimen.[33,82]

Defining the relationship between HIV, menopausal symptoms, and mental health is complicated because symptoms from HIV itself, effects of ART, and other comorbidities may overlap. Some studies suggest that women with HIV experience a greater burden of vasomotor symptoms, sexual dysfunction, and mood changes during menopause.[72,73,83] Other studies did not find differences between women with and without HIV.[84,85] Menopausal symptoms also have been associated with reduced adherence to ART and poor cognitive performance.[86-89]

No studies have shown evidence of estrogen deficiency (i.e., menopause) affecting CD4 count, plasma HIV viral loads, or response to ART.[90,91] Two small studies showed no difference in plasma levels of tenofovir and RAL between pre- and postmenopausal women.[92,93]

The use of HRT is low among women with HIV.[87] Data are limited on DDIs between ART and estradiol as part of HRT, and DDI data with ethinyl estradiol cannot be extrapolated to the estrogens used for HRT because of differences in metabolism. DDIs between HRT and ART are possible, particularly regimens containing COBI, RTV, protease inhibitors, and some NNRTIs. Clinicians are encouraged to check for DDIs by using the Liverpool HIV Drug Interaction Checker.

Knowledge Gaps

- More research is needed to assess sex differences in ART-related adverse effects, PK, adherence, aging, inflammation, and comorbidities.
- Research is needed on the interactions between LA ARV drugs and hormonal contraceptives and menopausal HRT.
- Research is needed among women of all ages—from adolescence to older adulthood—to evaluate the long-term safety and efficacy of newer ART, including LA injectables.
- More research is needed on the underlying mechanisms for weight gain in women with HIV taking ART and their impact on pregnancy outcomes, CVD, diabetes, and other age-related comorbidities.
- Research is needed to identify and implement the most effective strategies to support women's ART adherence and persistence throughout the lifespan.
- Research is needed on the impact of the use of pharmacologic interventions for ART-associated weight gain and related comorbidities in women.
- Research is needed on the effects of treatment of menopausal symptoms on ART adherence.

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