CLINICAL GUIDELINES PROGRAM
NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE | HIV • HCV • STIs • SUBSTANCE USE • LGBTQ+ HEALTH

HIV Testing During Pregnancy, at Delivery, and Postpartum

Updates, Authorship, and Related Resources

Date of current publication	September 9, 2022
Highlights of changes, additions, and updates in the September 9, 2022 edition	• Recommendation in Universal HIV Screening in Pregnancy updated: Using an FDA-approved HIV-1/2 Ag/Ab combination immunoassay and following the standard HIV testing algorithm, clinicians should screen all patients early in pregnancy, regardless of reported exposure, risk, or symptoms. (A2) • Recommendation in Testing for Acute HIV updated: If a patient's plasma HIV RNA test result indicates a viral load ≥5,000 copies/mL (or ≥200 copies/mL for patients taking PrEP or PEP), the clinician should make a presumptive diagnosis of acute HIV, even if the results of screening and HIV-1/HIV-2 Ab differentiation immunoassays are nonreactive or indeterminate. (A2) • New recommendation in Testing for Acute HIV: If a patient's viral load is detectable but lower than the levels stated above, to rule out acute HIV infection, the clinician should repeat the plasma HIV RNA test 2 weeks after the first test, preferably with a repeat HIV-1/2 Ag/Ab combination immunoassay. (A3) • Recommendations in Third Trimester HIV and Syphilis Testing updated: – Before 36 weeks' gestation (preferably between weeks 28 and 32), clinicians should repeat HIV testing for all patients with either a negative HIV test result or no documented HIV test result early in pregnancy. (A2) – Clinicians should repeat HIV testing in all pregnant patients who have engaged in behaviors that put them at risk of HIV acquisition during pregnancy or have acquired other STIs. (A2) • New recommendation in Third Trimester HIV and Syphilis Testing: Clinicians should repeat syphilis testing along with HIV testing in the third trimester in all pregnant patients. (A2) • Recommendation in PrEP to Prevent HIV updated: If a patient with a negative HIV test result requests PrEP or reports being at risk of HIV acquisition, clinicians should provide or promptly refer the patient for PrEP services. (A1) PrEP with TDF/FTC is not contraindicated during pregnancy or while breastfeeding an infant.
Intended users	New York State clinicians who provide care to pregnant individuals who are at risk of acquiring HIV
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Committee: Medical Care Criteria Committee
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Contents

Purpose of This Guideline

This guideline was developed by the New York State Department of Health AIDS Institute (NYSDOH AI) to provide clinicians in NYS with evidence-based recommendations for HIV testing of all pregnant patients, including those in labor.

The purpose is to promote universal HIV screening in pregnancy to ensure timely diagnosis of HIV and rapid initiation of antiretroviral therapy, which can prevent perinatal transmission and protect the health of patients and their infants. To meet these goals, this guideline emphasizes the following:

- In each pregnancy, HIV testing is recommended as early as possible and again during the third trimester.
- Expedited HIV testing during labor is required for patients without documented negative HIV status and is recommended for patients with risk factors for HIV infection.
- Third-trimester syphilis testing is recommended for all patients, to be performed at the same time as third-trimester HIV testing.
- HIV testing is recommended for any patient who presents with signs or symptoms of acute HIV infection during pregnancy or postpartum as well as for those with newly diagnosed sexually transmitted infections.
- Pre-exposure prophylaxis and post-exposure prophylaxis are available and recommended for pregnant and postpartum patients with negative HIV test results who are at high risk of acquiring HIV.

Note on "experienced" HIV care providers: The NYSDOH AI Clinical Guidelines Program defines an "experienced HIV care provider" as a practitioner who has been accorded HIV Specialist status by the American Academy of HIV Medicine. Nurse practitioners (NPs) and licensed midwives who provide clinical care to individuals with HIV in collaboration with a physician may be considered experienced HIV care providers if all other practice agreements are met; NPs with more than 3,600 hours of qualifying experience do not require collaboration with a physician (8 NYCRR 79-5:1; 10 NYCRR 85.36; 8 NYCRR 139-6900). Physician assistants who provide clinical care to individuals with HIV under the supervision of an HIV Specialist physician may also be considered experienced HIV care providers (10 NYCRR 94.2).

Universal HIV Screening in Pregnancy

☑ RECOMMENDATIONS

Universal HIV Screening in Pregnancy

- Using an FDA-approved HIV-1/2 Ag/Ab combination immunoassay and following the standard HIV laboratory testing algorithm, clinicians should screen all patients early in pregnancy, regardless of reported exposure, risk, or symptoms. (A2)
- Clinicians should refer patients who test positive for HIV to an experienced HIV care provider [a] who can manage ART initiation, ideally within 3 days. (A3)

Testing for Acute HIV

- When a patient presents with symptoms suggestive of acute HIV infection, the clinician should perform an HIV test immediately, even if a previous HIV screening test result during the current pregnancy was nonreactive. (A2)
- Clinicians should maintain a high level of suspicion for acute HIV in all pregnant patients who present with a compatible clinical syndrome. (A3)
- When screening for acute HIV, clinicians should obtain plasma HIV RNA testing in conjunction with HIV serologic testing, preferably with an HIV-1/2 Ag/Ab combination immunoassay; the plasma HIV RNA test should be performed even if the HIV serologic screening test result is nonreactive or indeterminate. (A2)
- If a patient's plasma HIV RNA test result indicates a viral load ≥5,000 copies/mL (or ≥200 copies/mL for patients taking PrEP or PEP), the clinician should make a presumptive diagnosis of acute HIV, even if the results of screening and HIV-1/HIV-2 Ab differentiation immunoassays are nonreactive or indeterminate. (A2)
- If a patient's viral load is detectable but lower than the levels stated above, to rule out acute HIV infection, the clinician should repeat the plasma HIV RNA test 2 weeks after the first test, preferably with a repeat HIV-1/2 Ag/Ab combination immunoassay. (A3)

Third Trimester HIV and Syphilis Testing

- Before 36 weeks' gestation (preferably between weeks 28 and 32), clinicians should repeat HIV testing for all patients with either a negative HIV test result or no documented HIV test result early in pregnancy. (A2)
- Clinicians should repeat HIV testing in all pregnant patients who have engaged in behaviors that put them at risk of HIV acquisition during pregnancy or have acquired other STIs. (A2)
- Clinicians should repeat syphilis testing along with HIV testing in the third trimester in all pregnant patients. (A2)

PrEP to Prevent HIV

- If a patient with a negative HIV test result requests PrEP or reports being at risk of HIV acquisition, clinicians should provide or promptly refer the patient for PrEP services. (A1) PrEP with TDF/FTC is not contraindicated during pregnancy or while breastfeeding an infant.

Abbreviations: Ab, antibody; Ag, antigen; ART, antiretroviral therapy; CEI, Clinical Education Initiative; FDA, U.S. Food and Drug Administration; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection; TDF/FTC, tenofovir disoproxil fumarate/emtricitabine.

Note:

a. **CEI Line for expert consultation:** Clinicians in New York State can speak with an experienced HIV care provider 24/7 regarding maternal or fetal HIV exposure by calling the CEI Line: 1-866-637-2342, option 2.

★ NEW YORK STATE LAW

- Clinicians in prenatal care settings must provide HIV-related information and recommend HIV testing for all pregnant patients, including those who present in labor if their HIV status is not documented.
- Immediately arrange an expedited HIV test, with consent, for patients in labor when no HIV test result is documented for the current pregnancy, with results available as soon as possible.

★ NEW YORK STATE LAW

- Any patient who does not have a documented HIV test result during the current pregnancy and who is not known to have HIV must, with their consent, receive expedited HIV testing during labor; results must be available within 12 hours of consent and preferably within 60 minutes. All birth facilities must have the capacity to provide and perform expedited HIV testing.
  - Facilities should use a U.S. Food and Drug Administration-approved HIV screening test, with results available preferably within 1 hour and no longer than 12 hours; the most sensitive screening test available should be used to allow for detection of early or acute HIV.
  - Ensure that expedited HIV test results are available prior to delivery to allow maximum benefits of intrapartum antiretroviral prophylaxis for the fetus.
  - Supplemental diagnostic testing must be obtained for all preliminary positive HIV test results in pregnant patients.
  - If a patient who presents in labor declines an HIV test, the infant is required to have an expedited HIV antibody screen at birth, with or without consent, with results available as soon as possible but no later than 12 hours after birth.
  - If the infant HIV test is reactive for HIV antibodies, a plasma sample should be collected from the infant for HIV-1 nucleic acid testing (see New York Codes, Rules and Regulations (NYCRR) Title 10, Section 69-1.3).
  - The DOH-4068 Maternal-Pediatric HIV Prevention and Care Program Test History and Assessment form must be completed for every pregnant individual presenting for delivery.
- The hospital shall determine the need for, and ensure provision of, HIV prophylaxis and/or treatment per standard of care to prevent transmission to the infant and shall record such in both the birth parent's and newborn's health records (see NYCRR Title 10, Section 405.21).
- Clinicians must discuss partner notification with patients who have been recently diagnosed with HIV, and the discussion must be documented in the medical record and on the Medical Provider Reporting Form (DOH-4189), as required by Public Health Law, Article 21, Title 3, Section 2130.

To help ensure timely diagnosis of HIV and implementation of effective measures to prevent perinatal transmission of HIV, New York State public health law mandates that all prenatal care settings regulated by the NYSDOH—including hospitals, diagnostic and treatment centers, health maintenance organizations, and birthing centers—provide information about HIV and recommend HIV testing, preferably at the first prenatal visit, to all individuals who present for care. Settings not regulated by the NYSDOH, such as some private offices, should also provide information about HIV and recommend voluntary HIV testing in accordance with NYSDOH, U.S. Department of Health and Human Services, and American College of Obstetrics and Gynecology (ACOG) standards of care for all pregnant individuals [DHHS 2025; ACOG 2018].

Diagnosing HIV and initiating ART at the time of diagnosis are crucial to reducing the risk of perinatal HIV transmission and maintaining the health of pregnant patients. HIV screening at the first prenatal visit increases the likelihood that HIV will be diagnosed, ART will be initiated early during pregnancy, and viral suppression can be attained.

For pregnant patients who are diagnosed with HIV, clinicians can provide assistance with partner notification through direct referral to:

- New York State and County Health Department What Health Care Providers Need to Know about Partner Services
- New York City Department of Health Contact Notification Assistance Program

More information on partner notification assistance and resources is also available at HIV/AIDS Laws and Regulations.

Testing for Acute HIV

Repeat HIV testing in patients who have a negative HIV test result early in pregnancy and assessment for acute HIV during pregnancy are important for reducing the risk of perinatal HIV transmission. Between 2007 and 2018, 11 of 45 (24.4%) perinatal transmissions to infants in New York State were associated with acute HIV infection acquired during pregnancy or the postpartum period through breastfeeding [NYSDOH 2019].

When a pregnant patient presents with symptoms suggestive of acute HIV, a plasma HIV RNA assay should be performed in conjunction with an HIV serologic screening test to diagnose acute HIV. An HIV-1/2 Ag/Ab combination immunoassay is the recommended serologic test.

For specific recommendations and expanded guidance on diagnosing and managing acute HIV, see the NYSDOH AI guideline Diagnosis and Management of Acute HIV Infection.

Third Trimester HIV and Syphilis Testing

Throughout New York State, clinicians who provide perinatal care should perform additional HIV testing in the third trimester for all pregnant patients with an initial negative HIV test result or no prior documented HIV test result. Approximately 80% of perinatal HIV transmissions occur after week 36 [Kourtis, et al. 2001]; therefore, this committee recommends HIV testing be performed between weeks 28 and 32 so that HIV testing can be performed concurrently with syphilis testing (see discussion of syphilis testing, below).

The Centers for Disease Control and Prevention (CDC) and ACOG recommend repeat HIV testing in the third trimester (before week 36) in areas with high incidence or prevalence of HIV; New York State is an area of high HIV prevalence [Workowski, et al. 2021; ACOG 2018], and some experts have argued that third-trimester testing should be universal [Cassimatis, et al. 2021]. Additionally, the CDC recommends repeat testing for chlamydia, gonorrhea, and syphilis in the third trimester if the patient is at risk [Workowski, et al. 2021]; in light of increasing rates of congenital syphilis, the ACOG recommends repeat syphilis testing for all pregnant individuals in the third trimester regardless of risk [ACOG 2024]. Assessment for acute HIV is strongly recommended in patients who present with compatible symptoms *at any time during pregnancy*.

Syphilis testing: The NYSDOH highly recommends that clinicians obtain serologic screening for syphilis for all pregnant patients at the first prenatal visit, during the third trimester (28 to 32 weeks of gestation), and at delivery (see also CDC 2021 STI Treatment Guidelines and Recommended Clinician Timeline for Screening for Syphilis, HIV, HBV, HCV, Chlamydia, and Gonorrhea).

PrEP to Prevent HIV

In addition to HIV screening as part of routine antenatal care, other prevention strategies should be available to pregnant and breastfeeding patients who are at high risk of acquiring HIV, including assessment for PrEP candidacy. PrEP significantly decreases the risk of HIV transmission in heterosexual serodifferent couples [Baeten, et al. 2012].

Although available data suggest that the use of tenofovir disoproxil fumarate/emtricitabine (TDF/FTC; brand name Truvada) as PrEP does not increase the risk of congenital anomalies, studies of bone mineral density (BMD) in infants born to women taking TDF-containing antiretroviral regimens have provided conflicting results [Mofenson, et al. 2017; Siberry, et al. 2015; Vigano, et al. 2011]. One study suggested a decrease in BMD of up to 15% in infants exposed to TDF in utero compared with infants who were not exposed to TDF [Siberry, et al. 2015], whereas another study found no association between in utero TDF exposure and infant BMD [Vigano, et al. 2011].

→ KEY POINTS

- **Routine STI screening in pregnancy:** Routine screening for chlamydia, gonorrhea, and syphilis can be combined with HIV testing at the initial visit and at 28 to 32 weeks gestation.
- **Sex partner STI testing:** This Committee encourages healthcare providers to recommend HIV testing for sex partner(s) of pregnant patients. During the first prenatal visit, when a clinician provides counseling about HIV and other health conditions, the care provider can suggest that a patient's sex partner(s) undergo testing for HIV. The same suggestion can be made if a patient is diagnosed with a new STI or reports having new sex partners during pregnancy. Whenever possible, the clinician should offer direct linkage to HIV testing and prevention services for partners.
- **Universal hepatitis C virus (HCV) screening:** The NYSDOH AI currently recommends universal HCV screening during each pregnancy.
- **PrEP:** For patients who report behavior that places them at risk for HIV acquisition, a negative HIV test result is an opportunity to encourage PrEP use. When used as prescribed, PrEP effectively prevents HIV acquisition.
  - TDF/FTC is the preferred PrEP regimen during pregnancy and while breastfeeding.
  - When indicated, PrEP is an effective component of a comprehensive HIV prevention plan that includes counseling and education about adherence to PrEP medications, ongoing monitoring with laboratory tests, and discussion of risk-reduction strategies.
  - Repeat screening for HIV and other STIs (chlamydia, gonorrhea, and syphilis) is part of routine PrEP management (see CDC 2021 STI Treatment Guidelines).
  - The use of antiretroviral medications during pregnancy is monitored through the Antiretroviral Pregnancy Registry.
- **CEI Line for expert consultation:** Clinicians in New York State can speak with an experienced HIV care provider 24/7 regarding maternal or fetal HIV exposure by calling the CEI Line: 1-866-637-2342, option 2.

HIV Testing During Labor and in Newborns

☑ RECOMMENDATIONS

HIV Testing and Prophylaxis During Labor and in Newborns

- When a patient in labor is not known to have HIV, does not have a documented third-trimester negative HIV test result, has been diagnosed with a sexually transmitted infection during pregnancy, or reports exposure risk for themselves or sex partners, the clinician should perform expedited HIV testing with consent and discuss the use of antiretroviral prophylaxis for the patient and the newborn [a]. (A2)
- If the result of the expedited HIV screening test for a patient in labor is reactive, the clinician should:
  - Obtain HIV diagnostic testing according to the standard HIV laboratory testing algorithm. (A1)
  - Initiate maternal antiretroviral prophylaxis (A1); immediate initiation is recommended. (A3)
  - Administer newborn prophylaxis [b] as soon as possible after birth. (A2)
- If supplemental diagnostic testing confirms that a patient in labor has HIV, the clinician should:
  - Ensure that an HIV diagnostic test of the infant is obtained within 48 hours of birth. The infant's specimen should be sent to the Pediatric HIV Testing Service at the Wadsworth Center for a nucleic acid test (NAT) to detect HIV-1 RNA or DNA. (B3)
  - Make arrangements for the patient with newly diagnosed HIV to see an experienced HIV care provider and, if indicated, provide referrals for case management and support services [c]. (A3)
  - Ensure that the HIV-exposed infant is discharged from care with antiretroviral medications in hand, not just a prescription. (B3)
  - Make arrangements for the infant's medical follow-up with an experienced pediatric HIV care provider. (A3)

Notes:

a. **Clinical Education Initiative (CEI) Line for expert consultation:** Clinicians in New York State can speak with an experienced HIV care provider 24/7 regarding maternal or fetal HIV exposure by calling the CEI Line: 1-866-637-2342, option 2.
b. See U.S. Department of Health and Human Services Recommendations for the Use of Antiretroviral Drugs in During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States > Management of Infants Born to People With HIV Infection.
c. See NYSDOH AI HIV Testing, Reporting and Confidentiality in New York State 2017-18 Update: Fact Sheet and Frequently Asked Questions > FAQ 11.

U.S. Food and Drug Administration (FDA)-approved HIV-1/2 antigen/antibody combination immunoassays are recommended for expedited HIV testing during labor and delivery. These tests screen for HIV-1 and HIV-2 antibodies and the HIV-1 p24 antigen. Because the p24 antigens produced by the virus may be detectable before an individual produces antibodies, combination immunoassays are capable of detecting acute HIV-1.

HIV testing of pregnant patients and their infants in the peripartum period functions as a safety net, ensuring screening for the small number of individuals not tested earlier in pregnancy or who seroconverted during pregnancy after the initial negative HIV test result.

Preliminary positive HIV test results: Although not diagnostic of HIV, most preliminary positive HIV test results are true-positive results; the precise ratio of true-positive to false-positive test results will depend on the test used and the local prevalence of HIV. When a preliminary positive result from a rapid HIV test occurs during labor and delivery, a second rapid test may be performed using a different FDA-approved rapid test device to obtain quick verification of the initial result. If both rapid HIV test results are reactive, the likelihood of infection is high. Regardless of whether 1 or 2 rapid HIV tests are performed, supplemental testing after a preliminary positive result is required to establish a diagnosis of HIV (see the standard HIV laboratory testing algorithm for maternal testing). Clinicians should collect a plasma sample from infants with a preliminary positive result and should obtain an HIV-1 NAT.

Antiretroviral prophylaxis for pregnant patients is more likely to benefit the infant when started as soon as a patient tests positive for HIV; the benefit of infant prophylaxis decreases when initiation is delayed [Fiscus, et al. 1999; Wade, et al. 1998]. These factors underscore the importance of initiating antiretroviral prophylaxis in pregnant patients and their infants as soon as possible and highlight the need for ongoing assessment of risk and HIV screening for patients who breastfeed. For specific

prophylaxis regimens, see U.S. Department of Health and Human Services Recommendations for Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States.

→ KEY POINTS

- Maternal HIV acquisition and acute infection confer a significant risk of HIV transmission to an infant who is being breastfed. Of maternal seroconversion-associated transmissions that occurred between 2007 and 2018, 4 of 11 were attributed to breastfeeding among women who acquired HIV early postpartum [NYSDOH 2019].
- The peripartum period is the final opportunity to provide antiretroviral prophylaxis and decrease the risk for perinatal HIV transmission to exposed infants of individuals who have not been previously identified as having HIV.
- As in the prenatal and peripartum periods, when a breastfeeding patient presents with symptoms suggestive of acute HIV infection, the clinician should perform an HIV test in conjunction with a plasma HIV RNA test immediately, even if previous HIV screening tests were nonreactive.
- Providing information about HIV and recommending HIV testing as early as possible in pregnancy is ideal.
- Per New York State Law, if a patient who presents in labor declines an HIV test, the infant is required to have an expedited HIV antibody screen at birth, with or without consent, with results available as soon as possible but no later than 12 hours after birth.

→ SELECTED GOOD PRACTICE REMINDERS

HIV Testing and Prophylaxis During Labor and in Newborns

- If the result of the expedited HIV test for a patient in labor is reactive:
  - Discuss the meaning of a preliminary positive HIV test result.
  - Do not delay prophylaxis while awaiting results of confirmatory serologic testing.
  - Inform the birth parent that HIV can be transmitted through breast milk and that breastfeeding is contraindicated until they are confirmed to be HIV negative. Refer the birth parent to a lactation specialist to assist with education and support for maintenance of breast milk supply, if so desired, so breastfeeding may be initiated if HIV infection is excluded.
- Provide education about the benefits of antiretroviral prophylaxis for any patient with HIV who declines it for themselves or their newborn.

HIV Testing and Management Checklist

Checklist for HIV Testing and Prophylaxis During Labor and in Newborns
From the New York State Department of Health AIDS Institute guideline *HIV Testing During Pregnancy, at Delivery, and Postpartum*. www.hivguidelines.org. September 2022

Repeat HIV Testing

- For patients in labor who do not have documented third-trimester HIV test results, have been diagnosed with a sexually transmitted infection during pregnancy, or report exposure risk for themselves or sex partners, perform expedited HIV testing with consent and discuss the use of antiretroviral (ARV) prophylaxis for the patient and the newborn.

Provide Counseling and Education About ARV Prophylaxis

- Counsel regarding the use of ARV prophylaxis in the birth parent and the infant.
- Provide education about the benefits of ARV prophylaxis for any patient with HIV who declines it for themselves or their newborn.

Manage a Reactive HIV Screening Test Result

- Obtain HIV diagnostic testing according to the standard HIV laboratory testing algorithm.
- Initiate maternal ARV prophylaxis; immediate initiation is recommended.
- Administer newborn prophylaxis as soon as possible after birth. See U.S. Department of Health and Human Services *Management of Infants Born to People with HIV Infection*.
- Discuss the meaning of a preliminary positive HIV test result.
- Do not delay prophylaxis while awaiting results of confirmatory serologic testing.
- Inform the birth parent that HIV can be transmitted through breast milk and that breastfeeding is not recommended until they are confirmed to be HIV negative.

Manage a Confirmed HIV Diagnosis in the Parent

- If supplemental diagnostic testing confirms that a patient in labor has HIV, ensure an HIV diagnostic test of the infant is obtained within 48 hours of birth. Send the infant's specimen to the Pediatric HIV Testing Service at the Wadsworth Center for nucleic acid testing to detect HIV-1 RNA or DNA.
- Make arrangements for the patient with newly diagnosed HIV to see an experienced HIV care provider and, if indicated, provide referrals for case management and support services.
- Ensure that the HIV-exposed infant is discharged from care with ARV medications in hand, not just a prescription.
- Make arrangements for the infant's medical follow-up with an experienced pediatric HIV care provider.

Resources

- Wadsworth Center Order Desk to Obtain a Pediatric HIV Test Kit: 518-474-4175
- Clinical Education Initiative (CEI) Line: 866-637-2342
- NYSDOH AI Clinical Guidelines Program: www.hivguidelines.org

NEW YORK STATE LAW

- Clinicians in prenatal care settings must provide HIV-related information and recommend HIV testing for all pregnant patients, including those who present in labor if their HIV status is not documented.
- Immediately arrange an expedited HIV test, with consent, for patients in labor when no HIV test result is documented for the current pregnancy, with results available as soon as possible.
- If a patient who presents in labor declines an HIV test, the infant is required to have an expedited HIV antibody screen at birth, with or without consent, with results available as soon as possible but no later than 12 hours after birth.
- If the infant's HIV test is reactive for HIV antibodies, a plasma sample should be collected from the infant for HIV-1 nucleic acid testing. (See *New York Codes, Rules and Regulations [NYCRR] Title 10, Section 69-1.3*.)
- The hospital shall determine the need for, and ensure provision of, HIV prophylaxis and/or treatment per standard of care to prevent transmission to the infant, and shall record such in both the birth parent's and newborn's health records. (See *NYCRR Title 10, Section 405.21*.)

All Recommendations

☑ ALL RECOMMENDATIONS: HIV TESTING DURING PREGNANCY, AT DELIVERY, AND POSTPARTUM

Universal HIV Screening in Pregnancy

- Using an FDA-approved HIV-1/2 Ag/Ab combination immunoassay and following the standard HIV laboratory testing algorithm, clinicians should screen all patients early in pregnancy, regardless of reported exposure, risk, or symptoms. (A2)
- Clinicians should refer patients who test positive for HIV to an experienced HIV care provider [a] who can manage ART initiation, ideally within 3 days. (A3)

Testing for Acute HIV

- When a patient presents with symptoms suggestive of acute HIV infection, the clinician should perform an HIV test immediately, even if a previous HIV screening test result during the current pregnancy was nonreactive. (A2)
- Clinicians should maintain a high level of suspicion for acute HIV in all pregnant patients who present with a compatible clinical syndrome. (A3)
- When screening for acute HIV, clinicians should obtain plasma HIV RNA testing in conjunction with HIV serologic testing, preferably with an HIV-1/2 Ag/Ab combination immunoassay; the plasma HIV RNA test should be performed even if the HIV serologic screening test result is nonreactive or indeterminate. (A2)
- If a patient's plasma HIV RNA test result indicates a viral load ≥5,000 copies/mL (or ≥200 copies/mL for patients taking PrEP or PEP), the clinician should make a presumptive diagnosis of acute HIV, even if the results of screening and HIV-1/HIV-2 Ab differentiation immunoassays are nonreactive or indeterminate. (A2)
- If a patient's viral load is detectable but lower than the levels stated above, to rule out acute HIV infection, the clinician should repeat the plasma HIV RNA test 2 weeks after the first test, preferably with a repeat HIV-1/2 Ag/Ab combination immunoassay. (A3)

Third Trimester HIV and Syphilis Testing

- Before 36 weeks' gestation (preferably between weeks 28 and 32), clinicians should repeat HIV testing for all patients with either a negative HIV test result or no documented HIV test result early in pregnancy. (A2)
- Clinicians should repeat HIV testing in all pregnant patients who have engaged in behaviors that put them at risk of HIV acquisition during pregnancy or have acquired other STIs. (A2)
- Clinicians should repeat syphilis testing along with HIV testing in the third trimester in all pregnant patients. (A2)

PrEP to Prevent HIV

- If a patient with a negative HIV test result requests PrEP or reports being at risk of HIV acquisition, clinicians should provide or promptly refer the patient for PrEP services. (A1) PrEP with TDF/FTC is not contraindicated during pregnancy or while breastfeeding an infant.

HIV Testing and Prophylaxis During Labor and in Newborns

- When a patient in labor is not known to have HIV, does not have a documented third-trimester negative HIV test result, has been diagnosed with a sexually transmitted infection during pregnancy, or reports exposure risk for themselves or sex partners, the clinician should perform expedited HIV testing with consent and discuss the use of antiretroviral prophylaxis for the patient and the newborn [a]. (A2)
- If the result of the expedited HIV screening test for a patient in labor is reactive, the clinician should:
  - Obtain HIV diagnostic testing according to the standard HIV laboratory testing algorithm. (A1)
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- If supplemental diagnostic testing confirms that a patient in labor has HIV, the clinician should:
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☑ ALL RECOMMENDATIONS: HIV TESTING DURING PREGNANCY, AT DELIVERY, AND POSTPARTUM

- Make arrangements for the patient with newly diagnosed HIV to see an experienced HIV care provider and, if indicated, provide referrals for case management and support services [c]. (A3)
- Ensure that the HIV-exposed infant is discharged from care with antiretroviral medications in hand, not just a prescription. (B3)
- Make arrangements for the infant's medical follow-up with an experienced pediatric HIV care provider. (A3)

Abbreviations: Ab, antibody; Ag, antigen; ART, antiretroviral therapy; CEI, Clinical Education Initiative; FDA, U.S. Food and Drug Administration; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection; TDF/FTC, tenofovir disoproxil fumarate/emtricitabine.

Note:

a. **CEI Line for expert consultation:** Clinicians in New York State can speak with an experienced HIV care provider 24/7 regarding maternal or fetal HIV exposure by calling the CEI Line: 1-866-637-2342, option 2.
b. See U.S. Department of Health and Human Services Recommendations for the Use of Antiretroviral Drugs in During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States > Management of Infants Born to People With HIV Infection.
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Supplement: Guideline Development and Recommendation Ratings

Table S1: Guideline Development: New York State Department of Health AIDS Institute Clinical Guidelines Program	
Developer	New York State Department of Health AIDS Institute (NYSDOH AI) Clinical Guidelines Program
Funding source	NYSDOH AI
Program manager	Clinical Guidelines Program, Johns Hopkins University School of Medicine, Division of Infectious Diseases. See Program Leadership and Staff.
Mission	To produce and disseminate evidence-based, state-of-the-art clinical practice guidelines that establish uniform standards of care for practitioners who provide prevention or treatment of HIV, viral hepatitis, other sexually transmitted infections, and substance use disorders for adults throughout New York State in the wide array of settings in which those services are delivered.
Expert committees	The NYSDOH AI Medical Director invites and appoints committees of clinical and public health experts from throughout New York State to ensure that the guidelines are practical, immediately applicable, and meet the needs of care providers and stakeholders in all major regions of New York State, all relevant clinical practice settings, key New York State agencies, and community service organizations.
Committee structure	• Leadership: AI-appointed chair, vice chair(s), chair emeritus, clinical specialist(s), JHU Guidelines Program Director, AI Medical Director, AI Clinical Consultant, AVAC community advisor • Contributing members • Guideline writing groups: Lead author, coauthors if applicable, and all committee leaders
Disclosure and management of conflicts of interest	• Annual disclosure of financial relationships with commercial entities for the 12 months prior and upcoming is required of all individuals who work with the guidelines program, and includes disclosure for partners or spouses and primary professional affiliation. • The NYSDOH AI assesses all reported financial relationships to determine the potential for undue influence on guideline recommendations and, when indicated, denies participation in the program or formulates a plan to manage potential conflicts. Disclosures are listed for each committee member.
Evidence collection and review	• Literature search and review strategy is defined by the guideline lead author based on the defined scope of a new guideline or update. • A comprehensive literature search and review is conducted for a new guideline or an extensive update using PubMed, other pertinent databases of peer-reviewed literature, and relevant conference abstracts to establish the evidence base for guideline recommendations. • A targeted search and review to identify recently published evidence is conducted for guidelines published within the previous 3 years. • Title, abstract, and article reviews are performed by the lead author. The JHU editorial team collates evidence and creates and maintains an evidence table for each guideline.
Recommendation development	• The lead author drafts recommendations to address the defined scope of the guideline based on available published data. • Writing group members review the draft recommendations and evidence and deliberate to revise, refine, and reach consensus on all recommendations. • When published data are not available, support for a recommendation may be based on the committee's expert opinion. • The writing group assigns a 2-part rating to each recommendation to indicate the strength of the recommendation and quality of the supporting evidence. The group reviews the evidence, deliberates, and may revise recommendations when required to reach consensus.

Table S1: Guideline Development: New York State Department of Health AIDS Institute Clinical Guidelines Program	
Review and approval process	• Following writing group approval, draft guidelines are reviewed by all contributors, program liaisons, and a volunteer reviewer from the AI Community Advisory Committee. • Recommendations must be approved by two-thirds of the full committee. If necessary to achieve consensus, the full committee is invited to deliberate, review the evidence, and revise recommendations. • Final approval by the committee chair and the NYSDOH AI Medical Director is required for publication.
External reviews	• External review of each guideline is invited at the developer's discretion. • External reviewers recognized for their experience and expertise review guidelines for accuracy, balance, clarity, and practicality and provide feedback.
Update process	• JHU editorial staff ensure that each guideline is reviewed and determined to be current upon the 3-year anniversary of publication; guidelines that provide clinical recommendations in rapidly changing areas of practice may be reviewed annually. Published literature is surveilled to identify new evidence that may prompt changes to existing recommendations or development of new recommendations. • If changes in the standard of care, newly published studies, new drug approval, new drug-related warning, or a public health emergency indicate the need for immediate change to published guidelines, committee leadership will make recommendations and immediate updates and will invite full committee review as indicated.

Table S2: Recommendation Ratings and Definitions		
Strength	**Quality of Evidence**	
A: Strong B: Moderate C: Optional	1	Based on published results of at least 1 randomized clinical trial with clinical outcomes or validated laboratory endpoints.
	*	Based on either a self-evident conclusion; conclusive, published, in vitro data; or well-established practice that cannot be tested because ethics would preclude a clinical trial.
	2	Based on published results of at least 1 well-designed, nonrandomized clinical trial or observational cohort study with long-term clinical outcomes.
	2†	Extrapolated from published results of well-designed studies (including nonrandomized clinical trials) conducted in populations other than those specifically addressed by a recommendation. The source(s) of the extrapolated evidence and the rationale for the extrapolation are provided in the guideline text. One example would be results of studies conducted predominantly in a subpopulation (e.g., one gender) that the committee determines to be generalizable to the population under consideration in the guideline.
	3	Based on committee expert opinion, with rationale provided in the guideline text.