HIV Testing During Pregnancy and at Delivery

Perinatal Transmission Prevention Guideline Committee, February 2017

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NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE | HIV • HCV • SUBSTANCE USE • LGBT HEALTH
Universal HIV Screening for Pregnant Women
Perinatal Transmission Prevention Guideline Committee, February 2017

RECOMMENDATIONS

**NYSDOH Regulation**
- Clinicians in prenatal care settings regulated by the NYSDOH must provide HIV-related information and recommend HIV testing for all women during pregnancy, including women presenting in labor if their status is not documented.

**Standard of Care**
- Clinicians should provide HIV-related information and recommend voluntary testing as a standard of care for all pregnant women. (A1)
- An FDA-approved 4th generation antigen/antibody combination immunoassay is recommended for screening. (A2)
  - See the NYSDOH AI guideline on HIV Testing > Steps in the HIV Diagnostic Testing Algorithm

To help ensure timely HIV diagnosis and implementation of effective measures to prevent mother-to-child transmission (MTCT) 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 HIV information and recommend HIV testing, preferably at the first prenatal visit, for all women who present for care. NYSDOH recommends that settings that are not regulated by NYSDOH, such as some private offices, provide HIV information and recommend voluntary testing in accordance with the NYSDOH and American College of Obstetrics and Gynecology (ACOG) standards of care for all pregnant women [AIDSinfo 2016; ACOG 2015].

**KEY POINTS**
- Identification of HIV infection and initiation of antiretroviral therapy (ART) at the time of diagnosis are crucial to reducing the risk of MTCT and maintaining maternal health.
- HIV screening at the first prenatal visit increases the likelihood that HIV infection will be diagnosed and ART will be initiated early in a woman's pregnancy and viral suppression can be attained.
- Completing HIV testing during the third trimester and *anytime an STI is diagnosed* increases identification of recent HIV infection.
- Routine screening for chlamydia, gonorrhea, and syphilis can be combined with HIV testing at the initial visit and in third trimester.
- Hepatitis C virus (HCV) screening should be performed in all pregnant individuals.

**References**
HIV Testing During the Third Trimester
Perinatal Transmission Prevention Guideline Committee, February 2017

**RECOMMENDATION**

- Clinicians should routinely recommend repeat testing in the third trimester, preferably between 34 and 36 weeks, for all women who test negative for HIV early in pregnancy (A2). This third-trimester repeat testing is strongly recommended for women who have continued risk behaviors during pregnancy or STIs. (A2)

The NYSDOH recommends that all prenatal care providers routinely recommend repeat HIV testing in the third trimester, preferably at 34 to 36 weeks, for all women who tested negative early in prenatal care [NYSDOH 2013]. The CDC and ACOG recommend repeat HIV testing in the third trimester in areas of high incidence or prevalence of HIV; New York State is listed as an area of high HIV prevalence [ACOG 2015; Branson et al. 2006]. The CDC and ACOG recommend repeat chlamydia, gonorrhea, and syphilis testing in the third trimester if the patient is at risk [ACOG 2015]. Assessment for acute HIV infection is strongly recommended in women presenting with compatible symptoms.

**References**


Testing for Acute HIV Infection During Pregnancy

Perinatal Transmission Prevention Guideline Committee, February 2017

RECOMMENDATIONS

- Clinicians should maintain a high level of suspicion for acute HIV infection in all pregnant women who present with a compatible clinical syndrome. Women who present with symptoms suggestive of acute HIV infection should be tested immediately, even if a previous HIV screening during the current pregnancy was nonreactive.
- When screening for acute infection, clinicians should obtain plasma HIV RNA testing in conjunction with HIV serologic testing, preferably with a 4th-generation HIV antigen/antibody combination test. The plasma RNA test should be performed even if the serologic screening test is nonreactive or indeterminate.
- Detection of HIV RNA with ≥5,000 copies/mL should be considered a presumptive diagnosis of acute infection even if the screening and antibody-differentiation tests are nonreactive or indeterminate. (A2)

NYSDOH data demonstrate the challenge of acute HIV infection in the increased risk of MTCT [NYSDOH AI; Patterson et al. 2007]. Repeat testing in women who test negative for HIV early in pregnancy, as well as assessment for acute infection during pregnancy, is important for reducing the risk of MTCT. Between 2007 and 2015, 9 (21.4%) of 42 perinatal transmissions to infants in New York State occurred among women who acquired HIV during pregnancy [NYSDOH AI].

Women who present with symptoms suggestive of acute HIV infection should receive a plasma HIV RNA assay in conjunction with an HIV serologic screening test to diagnose acute HIV infection. A 4th-generation HIV antigen/antibody combination assay is the recommended serologic test. For specific recommendations and expanded guidance on diagnosing and managing acute HIV infection, the NYSDOH AI guideline Diagnosis and Management of Acute HIV.

References

Identifying Women at Risk and Prescribing PrEP

Perinatal Transmission Prevention Guideline Committee, February 2017

**RECOMMENDATIONS**

- Clinicians should assess non-HIV-infected pregnant women for pre-exposure prophylaxis (PrEP) when the following risk factors for HIV acquisition are present:
  - A partner known to be infected with HIV (A1)
  - Injection drug use (A1)
  - A new diagnosis of a sexually transmitted infection (A1)
  - Multiple or anonymous sex partners (A1)

In addition to HIV screening as part of routine antenatal care, other prevention strategies should be available to pregnant women who are at high risk for HIV infection. Such women should be assessed for PrEP, which is a biomedical intervention using antiretroviral medications for non-HIV-infected individuals to reduce their risk of acquiring HIV infection. PrEP has been shown to be effective in significantly decreasing the risk of HIV transmission in heterosexual serodifferent couples [Baeten et al. 2012]. Data also demonstrate a 92% to 96% reduction in HIV transmission risk in serodifferent heterosexual relationships when the HIV-infected partner has been virally suppressed for at least 6 months [Donnell et al. 2010; Cohen et al. 2011].

Although available data suggest that PrEP using tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) does not increase the risk of birth defects, studies on bone mineral density in infants born to HIV-infected women receiving TDF–containing ART regimens have provided conflicting results [Siberry et al. 2015; Vigano et al. 2011]. One study suggested up to a 15% decrease in bone mineral density in infants exposed to TDF in utero when compared with infants who were not exposed to TDF, whereas another study found no association between in utero TDF exposure and infant bone mineral density [Vigano et al. 2011].

**KEY POINTS**

- PrEP should be prescribed as part of a comprehensive prevention plan that includes counseling and education about adherence to PrEP, ongoing monitoring with laboratory tests, and discussion of risk-reduction strategies (for more information regarding PrEP, the NYSDOH AI guideline PrEP to Prevent HIV Acquisition).
- Routine repeat screening for HIV and other sexually transmitted diseases (chlamydia, gonorrhea, and syphilis) is part of routine PrEP management.
- Prescription of PrEP for pregnant women who are at high risk for HIV infection is an individualized decision based on the safety, benefits, and risks associated with PrEP during pregnancy.
- The use of antiretroviral medications during pregnancy is being monitored through the Antiretroviral Pregnancy Registry.

**REFERENCES**


HIV Testing and Management for Women Presenting in Labor

Perinatal Transmission Prevention Guideline Committee, February 2017

\[ \text{NYSDOH REGULATIONS} \]

- Any woman without a documented HIV test result during the current pregnancy and not known to be HIV-infected must, with her consent, receive expedited HIV testing during labor, and results must be available within 12 hours of consent, preferably within 60 minutes. All birth facilities must have the capacity to provide and perform expedited HIV testing.
- Supplemental diagnostic testing must be obtained for all maternal preliminary positive HIV test results (the NYSDOH AI guideline HIV Testing > Steps in the HIV Diagnostic Testing Algorithm).
- If the mother declines HIV testing for herself, the infant must receive HIV antibody testing at birth, with results available as soon as possible but no longer than 12 hours after birth; HIV testing for the infant may be obtained without maternal consent.
- If the test performed on the infant is reactive for HIV antibodies, a plasma sample should be collected for HIV-1 nucleic acid testing (NYSDOH AI guideline Diagnosis of HIV in Exposed Infants).

\[ \text{RECOMMENDATIONS} \]

- Facilities should:
  - Use an FDA–approved HIV screening test that produces results 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 infection
  - Have expedited HIV test results available prior to delivery to allow maximum benefits of intrapartum ARV prophylaxis for the fetus
- Clinicians should offer and recommend repeat HIV testing during labor and delivery and counsel regarding the use of maternal and infant prophylaxis when the test is reactive for:
  - Any woman without known HIV infection who does not have documented third-trimester HIV test results (A2)
  - Any woman with continued risk behaviors or STIs during the current pregnancy (A2)
- If the result of the expedited HIV test is reactive, clinicians should:
  - Discuss the meaning of a preliminary positive HIV test result with the mother (A3)
  - Initiate maternal prophylaxis during labor (A1); immediate initiation is recommended (A3)
    - The NYSDOH AI guideline: Prevention of Mother–to–Child HIV Transmission
  - Administer newborn prophylaxis as soon as possible
    - The NYSDOH AI guideline: Care of the HIV–Exposed Infant of Indeterminate Status
  - Obtain maternal diagnostic testing according to the CDC algorithm (A1); prophylaxis should not be delayed while awaiting results of confirmatory serologic testing (A3)
    - The NYSDOH AI guideline: HIV Testing > Steps in the HIV Diagnostic Testing Algorithm
  - Inform the mother about the risk of postpartum MTCT via breast milk and that breastfeeding is contraindicated, even while receiving ARV prophylaxis, until HIV infection is excluded
- A woman who declines ARV prophylaxis for herself or her newborn should be educated about the benefits that ARV prophylaxis provides.
- If supplemental diagnostic testing confirms maternal HIV infection, clinicians should:
  - Make arrangements for the infant to receive HIV–related follow–up care prior to discharge from, or in consultation with, a pediatric provider who has experience with HIV management; this includes making arrangements for diagnostic testing to determine the infant’s HIV status; the first diagnostic specimen should be sent within 48 hours of birth to the Pediatric HIV Testing Service at the Wadsworth Center NYSDOH for HIV nucleic acid testing (NAT) to detect HIV–1 RNA or DNA
    - NYSDOH AI guideline: Diagnosis of HIV in Exposed Infants
  - Refer the mother for HIV care with a provider who has experience with HIV management
  - Provide the mother with referrals to HIV primary care and HIV–specific case management and support services
FDA-approved 4th generation HIV 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 for the HIV-1 p24 antigen. Because the p24 antigens produced by the virus may be detectable before an individual produces antibodies, 4th generation immunoassays are capable of detecting acute HIV-1 infection.

**KEY POINTS**

- The peripartum period is the final opportunity to provide ARV prophylaxis and decrease the risk for MTCT to HIV-exposed infants in mothers who have not been previously identified as HIV-infected.
- The ideal time for providing HIV information and testing is as early as possible in pregnancy.

HIV testing of women and/or their infants in the peripartum period is a “safety net” designed to screen the small number of women who were not tested earlier in pregnancy or who seroconverted during pregnancy after the initial negative HIV test.

**Preliminary positive test results:** Although not diagnostic of HIV infection, 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 infection. When a preliminary positive result from a rapid test occurs in the labor and delivery setting, 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 tests are reactive, the likelihood of infection is high. Regardless of whether one or two rapid tests are performed, supplemental testing after a preliminary positive result is required to establish a diagnosis of HIV infection (for maternal testing, see the NYSDOH AI guideline HIV Testing > Steps in the HIV Diagnostic Testing Algorithm). Clinicians should collect a plasma sample from infants with a preliminary positive result and should obtain HIV-1 nucleic acid testing (the NYSDOH AI guideline Diagnosis of HIV in Exposed Infants).

Maternal prophylaxis is more likely to be beneficial to the infant when started as soon as a woman presenting in labor screens positive for HIV, and the benefit of infant prophylaxis decreases when initiation is delayed [Wade et al. 1998; Fiscus et al. 1999]. These factors underscore the importance of initiating both maternal and infant prophylaxis as soon as possible. For specific prophylaxis regimens, the NYSDOH AI guideline Care of the HIV-Exposed Infant of Indeterminate Status and DHHS (AIDSinfo): Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States.

**References**


Partner Notification

**NYSDOH REGULATION**

- Clinicians must discuss partner notification with patients who have been recently diagnosed with HIV infection, and the discussion must be documented in the medical record and on the Medical Provider Reporting Form (DOH Form # 4189), as required by Public Health Law, Article 21, Title III, Section 213.

Clinicians can provide assistance with partner notification through direct referral to:
- The NYS and County Health Department Partner Services (PS) Programs
- The New York City Department of Health Contact Notification Assistance Program (CNAP)

More information on partner notification assistance and resources is also available at HIV/AIDS Laws & Regulations.
All Recommendations
Sexually Transmitted Infections Guidelines Committee, February 2018

✓ ALL RECOMMENDATIONS

NYSDOH Regulation
- Clinicians in prenatal care settings regulated by the NYSDOH must provide HIV–related information and recommend HIV testing for all women during pregnancy, including women presenting in labor if their status is not documented.

Standard of Care
- Clinicians should provide HIV–related information and recommend voluntary testing as a standard of care for all pregnant women. (A1)
- An FDA–approved 4th generation antigen/antibody combination immunoassay is recommended for screening. (A2)
  ▫ See the NYSDOH AI guideline HIV Testing > Steps in the HIV Diagnostic Testing Algorithm

Third Trimester HIV Testing
- Clinicians should routinely recommend repeat testing in the third trimester, preferably between 34 and 36 weeks, for all women who test negative for HIV early in pregnancy (A2). This third-trimester repeat testing is strongly recommended for women who have continued risk behaviors during pregnancy or STIs. (A2)

Acute HIV During Pregnancy
- Clinicians should maintain a high level of suspicion for acute HIV infection in all pregnant women who present with a compatible clinical syndrome. Women who present with symptoms suggestive of acute HIV infection should be tested immediately, even if a previous HIV screening during the current pregnancy was nonreactive.
- When screening for acute infection, clinicians should obtain plasma HIV RNA testing in conjunction with HIV serologic testing, preferably with a 4th-generation HIV antigen/antibody combination test. The plasma RNA test should be performed even if the serologic screening test is nonreactive or indeterminate.
- Detection of HIV RNA with ≥5,000 copies/mL should be considered a presumptive diagnosis of acute infection even if the screening and antibody–differentiation tests are nonreactive or indeterminate. (A2)

PrEP for Women at Risk of Acquiring HIV
- Clinicians should assess non–HIV–infected pregnant women for pre–exposure prophylaxis (PrEP) when the following risk factors for HIV acquisition are present:
  ▫ A partner known to be infected with HIV (A1)
  ▫ Injection drug use (A1)
  ▫ A new diagnosis of a sexually transmitted infection (A1)
  ▫ Multiple or anonymous sex partners (A1)

HIV Testing During Labor and Delivery
- Facilities should:
  ▫ Use an FDA–approved HIV screening test that produces results 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 infection
  ▫ Have expedited HIV test results available prior to delivery to allow maximum benefits of intrapartum ARV prophylaxis for the fetus
- Clinicians should offer and recommend repeat HIV testing during labor and delivery and counsel regarding the use of maternal and infant prophylaxis when the test is reactive for:
  ▫ Any woman without known HIV infection who does not have documented third-trimester HIV test results (A2)
  ▫ Any woman with continued risk behaviors or STIs during the current pregnancy (A2)

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HIV Testing During Labor and Delivery, continued

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  ▫ Discuss the meaning of a preliminary positive HIV test result with the mother (A3)
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  ▫ See the NYSDOH AI guideline: Prevention of Mother–to–Child HIV Transmission
  ▫ Administer newborn prophylaxis as soon as possible
    ▫ See the NYSDOH AI guideline: Care of the HIV–Exposed Infant of Indeterminate Status
  ▫ Obtain maternal diagnostic testing according to the CDC algorithm (A1); prophylaxis should not be delayed while awaiting results of confirmatory serologic testing (A3)
    ▫ See the NYSDOH AI guideline: HIV Testing > Steps in the HIV Diagnostic Testing Algorithm
  ▫ Inform the mother about the risk of postpartum MTCT via breast milk and that breastfeeding is contraindicated, even while receiving ARV prophylaxis, until HIV infection is excluded
  ▫ A woman who declines ARV prophylaxis for herself or her newborn should be educated about the benefits that ARV prophylaxis provides.

▪ If supplemental diagnostic testing confirms maternal HIV infection, clinicians should:
  ▫ Make arrangements for the infant to receive HIV–related follow–up care prior to discharge from, or in consultation with, a pediatric provider who has experience with HIV management; this includes making arrangements for diagnostic testing to determine the infant’s HIV status; the first diagnostic specimen should be sent within 48 hours of birth to the Pediatric HIV Testing Service at the Wadsworth Center NYSDOH for HIV nucleic acid testing (NAT) to detect HIV–1 RNA or DNA
    ▫ See the NYSDOH AI guideline: Diagnosis of HIV in Exposed Infants
  ▫ Refer the mother for HIV care with a provider who has experience with HIV management
  ▫ Provide the mother with referrals to HIV primary care and HIV–specific case management and support services

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