Maternal HIV Testing and Identification of Perinatal HIV Exposure

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Panel's Recommendations

- HIV testing is recommended as a standard of care for all sexually active people and should be a routine component of prepregnancy care (AII).
- All pregnant people should be tested as early as possible during each pregnancy (see Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations and 2018 Quick Reference Guide: Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens from the Centers for Disease Control and Prevention [CDC]) (AII).
- Partners of all pregnant people should be referred for HIV testing when their status is unknown (AIII).
- Repeat HIV testing in the third trimester is recommended for pregnant people with negative initial HIV tests who are at increased risk of acquiring HIV, including those receiving care in facilities that have an HIV incidence of ≥1 case per 1,000 pregnant women per year, those who reside in jurisdictions with elevated HIV incidence (see Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings from CDC), or those who reside in states or territories that require third-trimester testing (AII).
- Repeat HIV testing is recommended for pregnant people with a sexually transmitted infection or with signs and symptoms of acute HIV infection, or ongoing exposure to HIV (AIII). Referral for initiation of pre-exposure prophylaxis is recommended if HIV testing is negative (AIII). See Pre-Exposure Prophylaxis (PrEP) to Prevent HIV During Periconception, Antepartum, and Postpartum Periods for more information.
- Expedited[a] HIV testing should be performed during labor or delivery for people with undocumented HIV status and for those who tested negative early in pregnancy but are at increased risk of HIV infection and were not retested in the third trimester (AII). Testing should be available 24 hours a day, and results should be available within 1 hour. If results are positive, intrapartum intravenous zidovudine prophylaxis should be initiated immediately (AI); see Intrapartum Care for People With HIV.
- When a pregnant person has a positive HIV test result during labor and delivery or postpartum, or when a newborn's expedited antibody test is positive, supplemental HIV testing should be performed on the mother (an HIV-1/HIV-2 antibody differentiation assay and in most cases an HIV RNA assay) and the infant (HIV RNA assay) (AII); see Diagnosis of HIV Infection in Infants and Children for additional information.
- In these situations, an ARV regimen that is appropriate for infants who are at high risk of perinatal HIV transmission should be initiated immediately (AI). See Antiretroviral Management of Newborns With Perinatal HIV Exposure or HIV Infection for guidance.
- For persons who were planning to breastfeed, breastmilk should be expressed and stored appropriately until all supplemental HIV tests are reviewed and negative (AI).
- Pregnant people who were not tested for HIV before or during labor should undergo expedited HIV testing during the immediate postpartum period (or their newborns should undergo expedited HIV antibody testing) (AII).
- Results of maternal HIV testing should be documented in the newborn's medical record and communicated to the newborn's primary care provider (AIII).
- HIV testing is recommended for infants and children in foster care and adoptees for whom maternal HIV status is unknown to identify perinatal HIV exposure and possible HIV infection (AIII) (see Diagnosis of HIV Infection in Infants and Children).

[a] The term "expedited" is used to designate HIV testing performed in situations when a very short turnaround time is optimal. Expedited testing is dependent on the available HIV tests in each facility and may include antigen/antibody immunoassays, antibody-only assays, or HIV nucleic acid tests; see Approved HIV Tests in the text below.

Rating of Recommendations: A = Strong; B = Moderate; C = Optional

Rating of Evidence: I = One or more randomized trials in children† with clinical outcomes and/or validated endpoints; I = One or more randomized trials in adults with clinical outcomes and/or validated laboratory endpoints with accompanying data in children† from one or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; II = One or more well-designed, nonrandomized trials or observational cohort studies in children† with long-term outcomes; II* = One or more well-designed, nonrandomized trials or observational studies in adults with long-term clinical outcomes with accompanying data in children† from one or more similar nonrandomized trials or cohort studies with clinical outcome data; III = Expert opinion*

†Studies that include children or children and adolescents, but not studies limited to postpubertal adolescents

HIV Testing in Pregnancy

HIV infection should be identified before pregnancy (see Prepregnancy Counseling and Care for Persons of Childbearing Age With HIV) or as early as possible in pregnancy. In the United States, approximately 20% to 34% of infants with perinatal HIV exposure were born to people whose HIV diagnosis was not known before pregnancy.[1] Early diagnosis provides the best opportunity to improve the pregnant person's health and pregnancy outcomes and to prevent infant acquisition of HIV. Universal voluntary HIV testing is recommended as the standard of care for all pregnant people in the United States by the Panel on Antiretroviral Therapy and Medical Management of Children Living With HIV and the Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission (the Panels), the Centers for Disease Control and Prevention (CDC), the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, and the U.S. Preventive Services Task Force.[2-6] Providers should be aware that gaps in maternal HIV testing do occur and can contribute to missed opportunities for preventing perinatal HIV transmission.[7-10]

All HIV testing should be performed in a manner that is consistent with state and local regulations. CDC recommends the "opt-out" approach, which is allowed in many jurisdictions and involves notifying a pregnant person that HIV testing will be performed as part of routine care unless they choose not to be tested.[2] The "opt-in" approach involves obtaining specific consent before testing, and this approach has been associated with lower testing rates.[11,12] Despite the guidelines for universal HIV screening of pregnant people, recent studies indicate that fewer than 80% of women report having been tested for HIV during pregnancy.[13,14] The mandatory newborn HIV testing approach, which has been adopted by several states, involves testing newborns with or without maternal consent. In some areas, this applies to all newborns; in others, it applies only to the infants of mothers who have declined prenatal or intrapartum testing.

Approved HIV Tests and Recommended HIV Testing Algorithm

There are multiple U.S. Food and Drug Administration (FDA)-approved tests available for the diagnosis of HIV infection. Clinicians should familiarize themselves with the testing available at their facilities, including the turnaround time for receiving results. For the purposes of this section, three types of testing are discussed: antigen/antibody immunoassays; antibody only immunoassays; and HIV nucleic acid tests (NAT).

- Antigen/antibody immunoassays: Most routine laboratory testing for HIV currently uses antigen/antibody tests. Because these tests also detect HIV p24 antigen, they can detect acute HIV infection as early as 1 to 2 weeks after appearance of HIV RNA and before appearance of HIV antibody. These tests also detect HIV-2 infection. Laboratory-based tests require trained laboratory staff, and results can be available within 1 hour, but in some hospitals the test may not

be readily available 24 hours a day. One FDA-approved antigen/antibody test can be performed at the point of care (POC) and provides results within 30 minutes.

- Antibody-only immunoassays: Many antibody-only immunoassays in current use can be performed using blood from a finger stick or oral fluid and provide results within 30 minutes. Because of this very short turnaround time, they are often referred to as rapid tests. Many of these tests are also approved by the FDA for POC usage. Because these tests detect only antibody, acute HIV infection may be missed.
- HIV NAT: HIV-1 NAT tests detect HIV virus in blood. Depending on the type of HIV NAT, they may detect acute HIV infection, help diagnose HIV infection, and assess response to HIV therapy. Depending on the test, receiving results of an HIV-1 NAT may take several days. The HIV RNA assay is the preferred NAT for possible acute infection and perinatally acquired infection.

In this section, the term expedited is used to designate testing performed in situations when a very short turnaround time is optimal, such as when a mother is in labor but HIV status is undocumented. Expedited testing should be available in all delivery units 24 hours a day, and results should be available within 1 hour. Expedited testing is dependent on the available HIV tests in each facility and may include any of the three test types.

The Panels recommend that clinicians initiate HIV testing with an immunoassay that can detect HIV-1 antibodies, HIV-2 antibodies, and HIV-1 p24 antigen (referred to as an **HIV antigen/antibody immunoassay**). The Panels' recommendations for HIV testing are based on CDC's 2014 Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations.[15]

Individuals with a reactive antigen/antibody immunoassay should be tested further with an **HIV-1/HIV-2 antibody differentiation assay (referred to as supplemental testing).** Individuals with a reactive antigen/antibody immunoassay and a nonreactive differentiation test should be tested with an FDA-approved plasma HIV RNA assay to assess for acute HIV infection (see CDC's 2018 Quick Reference Guide: Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens).

In some clinical settings, initial testing may be conducted with a **rapid HIV test** which detects only HIV antibodies. Clinicians should assess a pregnant person's risk of acute HIV infection, particularly late in pregnancy, because people may receive a negative result for HIV immunoassays when they are in the window period (the time between infection and when the infection can be detected by a specific laboratory test). The antigen/antibody immunoassay may detect infection as early as 18 days after infection; antibody-only assays (such as rapid tests) may take as long 45 days. However, during this period, the person with acute HIV will be viremic,[16] with a high risk of perinatal transmission to the newborn. The HIV RNA assay can detect the presence of HIV as early as 10 days post-infection. **When acute HIV infection is suspected** during pregnancy, during the intrapartum period, or while breastfeeding, **a plasma HIV RNA assay should be performed in conjunction with an antigen/antibody immunoassay.** See Early (Acute and Recent) HIV Infection for more information.

Timing and Benefits of HIV Testing in Pregnancy

Maternal HIV testing should be performed as early as possible during pregnancy, wherever a person seeks care (including emergency departments and prenatal clinics), to avoid missed opportunities to identify pregnant people with HIV. Repeat HIV testing should be performed in the third trimester for people who are at increased risk of acquiring HIV or who are living in areas of high HIV incidence. Repeat testing is also recommended when pregnant individuals are diagnosed with sexually

transmitted infection (STI), or when they show symptoms and signs of acute HIV infection. Pregnant people with unknown or undocumented HIV status who present to care in labor should be tested before delivery or as soon as possible after delivery.[7-10] Because women are more susceptible to HIV acquisition during pregnancy and the postpartum period,[17] HIV testing provides an opportunity for clinicians to initiate a discussion about preventive interventions, including educating and counseling about pre-exposure prophylaxis (PrEP) for a pregnant person without HIV who is at risk for acquiring HIV. See Pre-Exposure Prophylaxis (PrEP) to Prevent HIV During Periconception, Antepartum, and Postpartum Periods and guidance available on CDC's Pre-Exposure Prophylaxis (PrEP) page for more information.

Determining an individual's HIV status before they become pregnant or during the antenatal period enables—

- People with HIV to receive appropriate antiretroviral therapy (ART) and prophylaxis against opportunistic infections;
- Initiation of treatment in the identified people to maintain and improve their health and to decrease risk of HIV transmission to their fetus and their partners[2,18,19];
- Referral of partners for testing, which allows the partners to initiate either treatment if the results are positive or preventive interventions, including PrEP, if the results are negative (see Pre-Exposure Prophylaxis (PrEP) to Prevent HIV During Periconception, Antepartum, and Postpartum Periods);
- Counseling of pregnant people with HIV about recommended modes of delivery based on individualized risks of perinatal transmission of HIV[20-22];
- Provision of an appropriate antiretroviral (ARV) drug regimen to the newborn to reduce the risk of perinatal transmission;
- Counseling regarding infant feeding for individuals with HIV (see Infant Feeding for Individuals With HIV in the United States); *and*
- Early diagnostic evaluation of infants exposed to HIV (see Diagnosis of HIV Infection in Infants and Children), as well as testing of other children, to permit prompt initiation of ART and any indicated prophylaxis measures.[3,23-25]

Discordant or False Positive HIV Tests

Discordant HIV testing results can be occur, requiring careful evaluation and often repeat tests. Early in HIV infection, before HIV seroconversion, the test combination of a positive antigen/antibody screen, negative HIV-1/HIV-2 antibody differentiation assay, and positive HIV RNA assay may be seen. This combination of results can occur because the immunoglobulin G–based antibody differentiation assay is positive later in infection than the antigen capture or the immunoglobulin M result in the antigen/antibody screen.

False-positive results do occur with HIV testing. The frequency of false-positive HIV testing is dependent on the prevalence of HIV in the population so may vary considerably. In a large urban hospital in Dallas, 21,163 women were screened using a combination antigen/antibody immunoassay and following the supplemental testing strategy recommended by the CDC algorithm. Of the 190 who tested positive, 28 were determined to have false-positive HIV yielding a positive predictive value of 83% (95% confidence interval [CI], 77-88%) and a false positive rate of 0.16% (95% CI, 0.11-0.22%), using the ARCHITECT HIV Ag/Ab assay.[26] For women screened a second time in pregnancy, the rate of false positive results relative to true positive results may be higher, as it

depends on the community risk of HIV acquisition over a short time period (i.e., the 6 months between first- and third-trimester testing).

For any positive HIV screen late in pregnancy or during labor, an HIV RNA assay should be done at the same time as the supplemental HIV-1/HIV-2 antibody differentiation assay, as the HIV RNA assay will be needed to resolve questions raised by discordant results between the antigen/antibody screen and the antibody differentiation assay.

The combination of a positive HIV antigen/antibody screen with a negative supplemental HIV-1/HIV-2 antibody differentiation assay and a negative HIV RNA assay is seen in people without HIV who have a false-positive antigen/antibody screen.

Repeat HIV Testing in the Third Trimester

Repeat HIV testing during the third trimester, before 36 weeks gestation, is recommended for people with negative results on their initial HIV tests during pregnancy who—

- Are at high risk of acquiring HIV (e.g., those who inject drugs or have sex with people who inject drugs, those who exchange sex for money or drugs, those who are sex partners of individuals with HIV, those who have had a new sex partner or more than one sex partner during the current pregnancy,[2] or those who have a suspected or diagnosed STI during pregnancy)[27]; *or*
- Are receiving health care in facilities where prenatal screening identifies one or more pregnant women with HIV per 1,000 women screened, or reside in a jurisdiction that has a high incidence of HIV in women between the ages of 15 and 45 years (see the 2006 Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings [PDF][a]);[2,27] *or*
- Reside in states or territories with statutes or regulations that require third-trimester testing. In a 2020 article, these included Arizona, Connecticut, Delaware, Florida, Georgia, Illinois, Louisiana, Maryland, Nevada, New Jersey, North Carolina, Tennessee, Texas, Virginia, and West Virginia.[28] Clinicians should check current requirements in their jurisdictions; *or*
- Have signs or symptoms of acute HIV (e.g., fever, lymphadenopathy, skin rash, myalgia, headaches, oral ulcers, leukopenia, thrombocytopenia, elevated transaminase levels).[2,27,29-31]

In addition, third-trimester testing should be offered to pregnant people who perceive themselves as being at increased risk for HIV infection (regardless of whether or not they fit any of the above criteria). Pregnant people who decline testing earlier in pregnancy should be offered testing again during the third trimester.

An antigen/antibody immunoassay should be used for third-trimester testing because these tests have a higher sensitivity in the setting of acute HIV infection than older antibody tests.[15,32] If acute HIV infection is suspected, a plasma HIV RNA assay should be performed in conjunction with an antigen/antibody immunoassay. See Early (Acute and Recent) HIV Infection for more information.

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[a] In 2004, these jurisdictions included Alabama, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Illinois, Louisiana, Maryland, Massachusetts, Mississippi, Nevada, New Jersey, New York, North Carolina, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Tennessee, Texas, and Virginia. Since that time, advances in HIV screening, prevention, and treatment have affected HIV diagnoses among reproductive-aged women, and some of these jurisdictions may no longer meet this incidence criterion.

Providers should be proactive in assessing a pregnant person's HIV acquisition risk and implementing third-trimester HIV retesting when indicated. A study in Baltimore found that only 28% of women were retested for HIV despite the high incidence of HIV in Maryland and a high frequency of clinical risk factors.[10] A study of data from 2007 to 2014 on children in Florida with perinatal HIV exposure found that perinatal HIV transmission was associated with poor or late prenatal care, diagnosis of HIV during labor and delivery or after birth, and, in some cases, acute maternal infection (as indicated by negative results for initial tests).[33] In a more recent study from a high-prevalence area in Florida, 91.7% of women had first- or second-trimester screening and, although only 82.2% had a third-trimester test, 89.3% of those without third-trimester screening had rapid testing upon admission.[34]

HIV Testing During Labor in People With Unknown HIV Status

People in labor whose HIV status is undocumented and those who tested negative early in pregnancy but are at increased risk of HIV infection and were not retested in the third trimester should undergo expedited HIV testing to identify HIV infection in pregnant persons and HIV exposure in their infants.[2-4,23,30,35,36]

- Perform an expedited HIV test—either an antigen/antibody immunoassay that can provide results within 1 hour or the most sensitive rapid test (includes rapid POC tests) available for persons in labor. An HIV RNA assay should also be performed for individuals with suspected acute HIV infection.
- If the initial HIV test result is negative (nonreactive), no further testing is required unless acute HIV infection is suspected (see Acute HIV Infection During Pregnancy or Breastfeeding below).[15]
- A positive antigen/antibody immunoassay or rapid HIV test result must be immediately followed by a supplemental HIV-1/HIV-2 antibody differentiation assay, as well as an HIV RNA assay for the mother and an HIV RNA assay for the infant.[15] If possible, contact the laboratory to prioritize results.
- For delivery units, every effort should be made to have the ability to run a confirmatory supplemental test (HIV-1/HIV-2 antibody differentiation assay) seven days a week. If possible, results of HIV RNA assays should be available in 24 hours or less.
- For individuals with a positive HIV test result or suspected acute HIV infection during labor, provide counseling about HIV test results and implications for care.
    - Initiate IV zidovudine during labor; see Intrapartum Care for People With HIV
    - Immediately initiate an ARV regimen that is appropriate for infants who are at high risk of perinatal HIV transmission (see Antiretroviral Management of Newborns With Perinatal HIV Exposure or Perinatal HIV or contact the National Clinician Consultation Center Perinatal HIV/AIDS hotline).
    - For persons who were planning to breastfeed, breastmilk should be expressed and stored appropriately until all supplemental HIV test results are reviewed and negative.

HIV Testing During the Postpartum Period

People who have not been tested for HIV before or during labor should be offered expedited testing during the immediate postpartum period. Postpartum HIV testing should be done using the antigen/antibody immunoassay to screen for established and acute HIV; results should be obtained in

<1 hour. If acute HIV infection is a possibility, then a plasma HIV RNA test should be sent as well. When mothers are unavailable for testing, their newborns should undergo HIV testing to assess perinatal HIV exposure using an antigen/antibody immunoassay. For infants testing positive, an HIV RNA assay should be sent immediately.[3,23,30] Postnatal ARV drugs need to be initiated as soon as possible—ideally ≤6 hours after birth—to be effective in preventing perinatal transmission. When an initial HIV test is positive in mothers or infants, it is strongly recommended that clinicians initiate an ARV regimen that is appropriate for infants who are at high risk of perinatal HIV transmission and counsel the mothers against breastfeeding pending the results of supplemental testing, which should include a plasma HIV RNA assay. Breast milk can be expressed while HIV diagnostic testing is being completed, but it should not be given to the infant until testing confirms that the mother is HIV negative (see Antiretroviral Management of Newborns With Perinatal HIV Exposure or Perinatal HIV). If supplemental test results are negative and acute HIV is excluded, infant ARV drugs can be discontinued. In the absence of ongoing maternal HIV exposure, breastfeeding can be initiated. Consultation with a pediatric HIV specialist is strongly recommended if questions remain about the potential for acute maternal infection or ongoing maternal HIV exposure.

Infant HIV Testing When Maternal HIV Test Results Are Unavailable

When maternal HIV test results are unavailable (e.g., the mother has declined testing during pregnancy or for infants and children who are in foster care) or their accuracy cannot be evaluated (e.g., for internationally adopted infants and children), HIV testing of these infants or children is indicated to identify HIV exposure and possible infection.[3] The choice of test will vary based on the age of the child (see Diagnosis of HIV Infection in Infants and Children). Mechanisms should be developed to facilitate prompt HIV screening for infants who have been abandoned and who are in the custody of the state.

Acute HIV Infection During Pregnancy or Breastfeeding

Women are more susceptible to HIV infection during pregnancy and the early postpartum period.[37] Risk of HIV exposure should be assessed in all people who are considering becoming pregnant, as well as in all pregnant and postpartum people who previously tested negative for HIV, including those who are breastfeeding. People with risk factors for HIV acquisition before, during, and after pregnancy should receive prevention counseling and appropriate interventions, including PrEP if indicated.[37,38] (See Prepregnancy Counseling and Care for Persons of Childbearing Age with HIV and Pre-Exposure Prophylaxis (PrEP) to Prevent HIV During Periconception, Antepartum, and Postpartum Periods for more information. People who have acute HIV during pregnancy or lactation have an increased risk of perinatal transmission and secondary sexual transmission of HIV (see Early (Acute and Recent) HIV Infection).[39-43] The antigen/antibody immunoassay will detect acute HIV infection earlier than other immunoassays—within approximately 18 days of acquisition. When acute HIV infection is suspected, a plasma HIV RNA test should be sent as well because virologic tests can detect the presence of HIV approximately 5 days earlier than the antigen/antibody immunoassay. People with possible acute HIV infection who are breastfeeding should cease breastfeeding immediately until HIV infection is confirmed or excluded.[44] Breast milk can be expressed while HIV diagnostic testing is completed. Breastfeeding can resume if HIV infection is excluded and there is no ongoing risk. Care of pregnant or breastfeeding people with acute or early HIV, and their infants, should follow the recommendations in the Perinatal Guidelines (see Early (Acute and Recent) HIV Infection, Antiretroviral Management of Newborns With Perinatal HIV Exposure or HIV Infection, and Infant Feeding for Individuals With HIV in the United States).

Other Issues

Clinicians should be aware of public health surveillance systems and regulations that may exist in their jurisdictions for reporting infants who have been exposed to HIV; this is in addition to mandatory reporting of people with HIV, including infants. Reporting infants who have been exposed to HIV allows the appropriate public health functions to be accomplished.

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