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WOMEN'S HEALTH CARE PHYSICIANS

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Committee on Obstetric Practice HIV Expert Work Group

This Committee Opinion was developed by the American College of Obstetricians and Gynecologists' Committee on Obstetric Practice and the HIV Expert Work Group.

INTERIM UPDATE: This Committee Opinion is updated as highlighted to reflect a limited, focused change in the language and evidence regarding opt-out testing, repeat testing, rapid testing, and hepatitis A testing.

Prenatal and Perinatal Human Immunodeficiency Virus Testing

ABSTRACT: Given the enormous advances in the prevention of perinatal transmission of human immunodeficiency virus (HIV), it is clear that early identification and treatment of all pregnant women with HIV is the best way to prevent neonatal infection and also improve women's health. Furthermore, **new** evidence suggests that early initiation of antiretroviral therapy in the course of infection is beneficial for individuals infected with HIV and reduces the rate of sexual transmission to partners who are not infected. Screening should be performed after women have been notified that HIV screening is recommended for all pregnant patients and that they will receive an HIV test as part of the routine panel of prenatal tests unless they decline (opt-out screening). Human immunodeficiency virus testing using the opt-out approach, which is currently permitted in every jurisdiction in the United States, should be a routine component of care for women during prepregnancy and as early in pregnancy as possible. Repeat HIV testing in the third trimester, preferably before 36 weeks of gestation, is recommended for pregnant women with initial negative HIV antibody tests who are known to be at high risk of acquiring HIV infection; who are receiving care in facilities that have an HIV incidence in pregnant women of at least 1 per 1,000 per year; who are incarcerated; who reside in jurisdictions with elevated HIV incidence; or who have signs and symptoms consistent with acute HIV infection (eg, fever, lymphadenopathy, skin rash, myalgias, arthralgias, headache, oral ulcers, leukopenia, thrombocytopenia, or transaminase elevation). Rapid screening during labor and delivery or during the immediate postpartum period using the opt-out approach should be done for women who were not tested earlier in pregnancy or whose HIV status is otherwise unknown. Results should be available 24 hours a day and within 1 hour. If a rapid HIV test result in labor is reactive, antiretroviral prophylaxis should be immediately initiated while waiting for supplemental test results. If the diagnosis of HIV infection is established, the woman should be linked into ongoing care with a specialist in HIV care for comanagement.

Recommendations

Given the enormous advances in the prevention of perinatal transmission of human immunodeficiency virus (HIV), it is clear that early identification and treatment of all pregnant women with HIV is the best way to prevent neonatal infection and also improve women's health. Therefore, the American College of Obstetricians and Gynecologists makes the following recommendations:

- Human immunodeficiency virus testing is recommended for all sexually active women or women

who use intravenous drugs and should be a routine component of prepregnancy and prenatal care.

- Human immunodeficiency virus testing using the opt-out approach, which is currently permitted in every jurisdiction in the United States, should be a routine component of care for women during prepregnancy and as early in pregnancy as possible.
- Repeat HIV testing in the third trimester, preferably before 36 weeks of gestation, is recommended for

pregnant women with initial negative HIV antibody tests who are known to be at high risk of acquiring HIV infection; who are receiving care in facilities that have an HIV incidence in pregnant women of at least 1 per 1,000 per year; who are incarcerated; who reside in jurisdictions with elevated HIV incidence; or who have signs or symptoms consistent with acute HIV infection (eg, fever, lymphadenopathy, skin rash, myalgias, arthralgias, headache, oral ulcers, leukopenia, thrombocytopenia, or transaminase elevation).

- Rapid screening during labor and delivery or during the immediate postpartum period using the opt-out approach should be done for women who were not tested earlier in pregnancy or whose HIV status is otherwise unknown. Results should be available 24 hours a day and within 1 hour.
- If a rapid HIV test result in labor is reactive, antiretroviral prophylaxis should be immediately initiated while waiting for supplemental test results.
- If the diagnosis of HIV infection is established, the woman should be linked into ongoing care with a specialist in HIV care for comanagement.

Introduction

The Centers for Disease Control and Prevention (CDC) reports approximately 40,000 individuals are diagnosed with HIV annually in the United States. From 2011 through 2016, the annual estimated number of diagnoses and rate of diagnoses of HIV infection in the United States remained stable (1, 2). These new HIV infections include approximately 99 infants infected by mother-to-child (vertical) transmission (2). Combined antiretroviral therapy can achieve a risk of 1–2% or less for maternal-to-child transmission if maternal viral loads of 1,000 copies/mL or less can be sustained, independent of the route of delivery or duration or ruptured membranes before delivery (3). Even instituting maternal prophylaxis during labor and delivery, neonatal prophylaxis within 24–48 hours of delivery, or both, can substantially decrease rates of infection in infants (4, 5). Furthermore, new evidence suggests that early initiation of antiretroviral therapy in the course of infection is beneficial for individuals infected with HIV and reduces the rate of sexual transmission to partners who are not infected (6, 7). Therefore, it is critical that pregnant women infected with HIV be accurately identified in a timely manner so that measures can be taken to decrease the risk of mother-to-child transmission of HIV as well as to optimize their own health. Human immunodeficiency virus testing using the opt-out approach, which is currently permitted in every jurisdiction in the United States, should be a routine component of care for women during prepregnancy and as early in pregnancy as possible (8). Rapid screening during labor and delivery or during the immediate postpartum period using the opt-out approach

should be done for women who were not tested earlier in pregnancy or whose HIV status is otherwise unknown. Results should be available 24 hours a day and within 1 hour.

The Evolution of Human Immunodeficiency Virus Testing

The conventional algorithm for HIV diagnosis, which involves a reactive antibody screening test followed by Western Blot confirmation, has been in place for more than 20 years. However, with the development of newer HIV tests, algorithms for testing are being revised in order to more accurately identify individuals infected with HIV (8, 9). Previous guidelines only used tests for HIV antibodies. Updated recommendations include tests for HIV antigens and HIV nucleic acid because studies from populations at high risk of HIV demonstrate that antibody testing alone might miss a considerable percentage of HIV infections that are detectable by virologic tests. These newer algorithms highlight the utility of HIV RNA testing; especially in early infections, when there is a discrepancy between initial and confirmatory testing, or both (see Box 1 in the CDC and the Association of Public Health Laboratories' publication "Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations" [9]).

Prenatal Human Immunodeficiency Virus Testing

Human immunodeficiency virus testing is recommended for all sexually active women or women who use intravenous drugs and should be a routine component of prepregnancy and prenatal care. All women should be screened for HIV infection before pregnancy. All HIV-negative women should be tested as early as possible during each pregnancy using the opt-out approach, which is currently permitted in every jurisdiction in the United States (8). This should involve using a newer, recommended antibody–antigen combination screening test. Screening should be performed after women have been notified that HIV screening is recommended for all pregnant patients and that they will receive an HIV test as part of the routine panel of prenatal tests unless they decline (opt-out screening). No woman should be tested without her knowledge; however, no additional process or written documentation of informed consent beyond what is required for other routine prenatal tests is recommended for HIV testing. Pregnant women should be provided with oral or written information about HIV that includes an explanation of HIV infection, a description of interventions that can reduce HIV transmission from mother to infant, the meanings of positive and negative test results, and the opportunity to ask questions and decline testing. If a patient declines HIV testing, this should be documented in the medical record and should not affect access to care. In addition, the obstetrician–gynecologist or other obstetric provider should discuss and address the patient's reasons for declining an HIV test. For example, a woman who declines an HIV test because she

has had a previous negative test result should be informed of the importance of retesting during each pregnancy (10). Continuing discussion at future encounters and again offering and encouraging testing may increase rates of antenatal screening.

The American College of Obstetricians and Gynecologists, the American Academy of Pediatrics (11), and the CDC (10) recommend opt-out HIV screening for pregnant women. Obstetrician-gynecologists and other obstetric care providers should be aware of and comply with their states' legal requirements for perinatal screening. The National HIV/AIDS Clinicians' Consultation Center at the University of California-San Francisco maintains an online compendium of state HIV testing laws and this listing can be a useful resource to those seeking to understand their state's regulations (see the For More Information section).

The Role of Rapid Human Immunodeficiency Virus Testing in Obstetrics

A rapid HIV test is an HIV screening test with quickly available results, ideally within 1 hour. Rapid tests include point of care tests performed outside a laboratory (eg, outpatient or labor and delivery setting) as well as testing performed in a laboratory, including rapid serologic testing. Obstetrician-gynecologists or other obstetric providers may use rapid testing as their standard outpatient test and also should use rapid testing in labor and delivery. A negative rapid test result is definitive unless very recent exposure to HIV has occurred or early HIV infection is suspected (in which case nucleic acid testing may be needed). A reactive rapid test result is not definitive and should be confirmed with a supplemental test. Rapid test results usually will be available during the same clinical visit that the specimen (eg, blood or oral swab) is collected. Obstetrician-gynecologists or other obstetric providers who use these tests should be prepared to provide counseling the same day as testing to pregnant women whose rapid test results are reactive. Pregnant women with reactive rapid test results should be counseled regarding the meaning of these preliminary positive test results and the need for confirmation. If the results of the rapid test and the supplemental test are discrepant, testing the sample for plasma HIV RNA is recommended (9).

Any woman who arrives at a labor and delivery facility with undocumented HIV status during the current pregnancy should be screened with a rapid HIV test unless she declines (opt-out screening) in order to provide an opportunity to begin prophylaxis before delivery if necessary (10). If a rapid test used in labor is reactive, immediate initiation of antiretroviral prophylaxis for mother and neonate should be recommended without waiting for the supplemental test results. All antiretroviral prophylaxis should be discontinued if supplemental testing concordant with cited guidelines is negative (12).

As described in *Guidelines for Perinatal Care*, Eighth Edition, the American Academy of Pediatrics advises that infants born to women with unknown HIV status should have expedited HIV testing performed as soon as possible after birth (13). Obstetrician-gynecologists or other obstetric providers should recognize, however, that because neonatal results simply reflect maternal status, requiring testing effectively removes the "opt out" option and makes HIV testing of pregnant women mandatory. ~~obstetrician-gynecologists or other obstetric providers should check their state requirements before recording HIV test results.~~ The usual ethical objections to mandatory testing are in this circumstance balanced by the benefit that early diagnosis and treatment bring for the neonate. Although learning maternal HIV status is a consequence of testing the neonate, it is not the primary intent, which is evaluating the newborn's health. Regardless of the testing protocol or paradigm, women should be informed of all tests performed on their neonates, and resources should be provided to appropriately and promptly treat women and neonates based on the results. Human immunodeficiency virus testing to determine HIV status is recommended for infants and children in foster care and adoptees for whom maternal HIV status is unknown; additionally, if women are unavailable for testing, their newborns should undergo expedited HIV testing (8).

Repeat Human Immunodeficiency Virus Testing in the Third Trimester

Repeat HIV testing in the third trimester, preferably before 36 weeks of gestation, is recommended for pregnant women with initial negative HIV antibody tests who are known to be at high risk of acquiring HIV infection; who are receiving care in facilities that have an HIV incidence in pregnant women of at least 1 per 1,000 per year; who are incarcerated; who reside in jurisdictions with elevated HIV incidence; or who have signs or symptoms consistent with acute HIV infection (eg, fever, lymphadenopathy, skin rash, myalgias, arthralgias, headache, oral ulcers, leukopenia, thrombocytopenia, or transaminase elevation) (14). When acute infection is possible, a plasma RNA test should be used in addition to standard testing for HIV antibodies.

~~Repeat testing in the third trimester, preferably before 36 weeks of gestation, is recommended for pregnant women at high risk of acquiring HIV.~~ Pregnant women at high risk of acquiring HIV include (10)

- those who have been diagnosed with another sexually transmitted disease in the past year.
- those who are injection drug users or whose sex partners are injection drug users.
- those who exchange sex for money or drugs.
- those women with a new sex partner, more than one sex partner during this pregnancy, or sex partners known to be infected with HIV or at high risk of HIV.

Giving Human Immunodeficiency Virus Test Results

If a pregnant woman's HIV test results are positive, the patient should be given her results in person. The implications of HIV infection and the risks of vertical and horizontal transmission should be discussed with the patient. Additional laboratory work, including CD4⁺ count; HIV viral load; testing for antiretroviral resistance; hepatitis C virus antibody; hepatitis B surface antigen and viral load; and hepatitis A using antibody testing for immunoglobulin G for women who have hepatitis B virus infection and who have not already received the hepatitis A virus vaccine series; complete blood count with platelet count; and baseline chemistries with comprehensive metabolic testing, will be useful before prescribing antiretroviral therapy. If the diagnosis of HIV infection is established, the woman should be linked into ongoing care with a specialist in HIV care for comanagement. Specific recommendations for the use of antiretroviral medications in pregnant women infected with HIV are available at www.aidsinfo.nih.gov and are frequently updated. In addition, the patient should be told about the importance of notifying her sexual partners about their exposure to HIV and the importance of HIV testing for any sexual partner. Partner notification can be challenging for patients and women because, in some cases, the women face the possibility of being ostracized by their respective families, friends, and community or being subjected to intimate partner violence (15). The CDC offers guidance for undertaking such notification (16). Obstetrician–gynecologists or other obstetric providers should be aware of and comply with their states' legal requirements regarding partner notification and disclosure of HIV results to others, including the infant's pediatrician (www.cdc.gov/hiv/policies/law/states).

For More Information

The American College of Obstetricians and Gynecologists has identified additional resources on topics related to this document that may be helpful for ob-gyns, other health care providers, and patients. You may view these resources at www.acog.org/HIV.

These materials are for information purposes only and are not meant to be comprehensive. Referral to these resources does not imply ACOG's endorsement of the organization, the organization's website, or the content of the resource. The resources may change without notice.

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