American Academy of Pediatrics
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POLICY STATEMENT

HIV Testing and Prophylaxis to Prevent Mother-to-Child Transmission in the United States

Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of All Children

Committee on Pediatric AIDS

ABSTRACT

Universal HIV testing of pregnant women in the United States is the key to prevention of mother-to-child transmission of HIV. Repeat testing in the third trimester and rapid HIV testing at labor and delivery are additional strategies to further reduce the rate of perinatal HIV transmission. Prevention of mother-to-child transmission of HIV is most effective when antiretroviral drugs are received by the mother during her pregnancy and continued through delivery and then administered to the infant after birth. Antiretroviral drugs are effective in reducing the risk of mother-to-child transmission of HIV even when prophylaxis is started for the infant soon after birth. New rapid testing methods allow identification of HIV-infected women or HIV-exposed infants in 20 to 60 minutes. The American Academy of Pediatrics recommends documented, routine HIV testing for all pregnant women in the United States after notifying the patient that testing will be performed, unless the patient declines HIV testing ("opt-out" consent or "right of refusal"). For women in labor with undocumented HIV-infection status during the current pregnancy, immediate maternal HIV testing with opt-out consent, using a rapid HIV antibody test, is recommended. Positive HIV antibody screening test results should be confirmed with immunofluorescent antibody or Western blot assay. For women with a positive rapid HIV antibody test result, antiretroviral prophylaxis should be administered promptly to the mother and newborn infant on the basis of the positive result of the rapid antibody test without waiting for results of confirmatory HIV testing. If the confirmatory test result is negative, then prophylaxis should be discontinued. For a newborn infant whose mother's HIV serostatus is unknown, the health care professional should perform rapid HIV antibody testing on the mother or on the newborn infant, with results reported to the health care professional no later than 12 hours after the infant's birth. If the rapid HIV antibody test result is positive, antiretroviral prophylaxis should be instituted as soon as possible after birth but certainly by 12 hours after delivery, pending completion of confirmatory HIV testing. The mother should be counseled not to breastfeed the infant. Assistance with immediate initiation of hand and pump expression to stimulate milk production should be offered to the mother, given the possibility that the confirmatory test result may be negative. If the confirmatory test result is negative, then prophylaxis should be stopped and breastfeeding may be initiated. If the confirmatory test result is positive, infants should receive antiretroviral prophylaxis for 6 weeks after birth, and the mother should not breastfeed the infant. *Pediatrics* 2008;122:1127–1134

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Key Words
human immunodeficiency virus, HIV, perinatal transmission, antiretroviral, prophylaxis, prevention, testing

Abbreviations
MTCT—mother-to-child transmission
AAP—American Academy of Pediatrics
ARV—antiretroviral
CDC—Centers for Disease Control and Prevention
EIA—enzyme immunoassay
IFA—immunofluorescent antibody
ZDV—zidovudine
ACOG—American College of Obstetricians and Gynecologists
USPHS—US Public Health Service

INTRODUCTION

Continuing technologic and medical advances in the diagnosis, prevention, and treatment of pediatric HIV infection require ongoing assessment and review of recommendations relating to pediatric HIV infection, including recommendations regarding prenatal and perinatal HIV counseling and testing. Current guidelines are consistent in their recognition of the importance of universal HIV testing of pregnant women in the United States as the key to prevention of mother-to-child transmission (MTCT) (also referred to as vertical or perinatal transmission) of HIV. The American Academy of Pediatrics (AAP) continues to support these guidelines. This policy statement updates the data that support the guidelines and suggests ways to continue improving the implementation of the recommendations for universal testing during routine prenatal care.

WHY IS A NEW STATEMENT NEEDED NOW?

There is continued MTCT of HIV in the United States; 397 infants were infected through MTCT in 1999–2001 in areas conducting enhanced perinatal surveillance.[1] These infant infections occurred despite the availability of efficacious

interventions for preventing such transmission (antiretroviral [ARV] prophylaxis to mother and infant, elective cesarean delivery before the onset of labor and before rupture of membranes, and complete avoidance of breastfeeding).[2] In recent years, lack of identification of maternal HIV-infection status has been the primary reason for new infant HIV infections; effective interventions cannot be implemented unless maternal HIV status is known. Rapid HIV antibody testing methods now allow identification of HIV-infected women or HIV-exposed infants in 20 to 60 minutes[3–5] (see also www.cdc.gov/hiv/topics/testing/rapid/index.htm). Studies have demonstrated the effectiveness of ARV prophylaxis for preventing MTCT of HIV, even when prophylaxis is initiated after the birth of the infant.[6–10] New guidelines from the Centers for Disease Control and Prevention (CDC) strengthen the recommendations for routine HIV testing during pregnancy.[11] This report summarizes the recommendations of the AAP regarding HIV testing and prophylaxis to prevent MTCT of HIV, which are consistent with and supportive of the CDC recommendations.

HIV TESTING

For adults and children 18 months or older, "conventional testing" of blood for the presence of antibodies against HIV is performed by using a screening enzyme immunoassay (EIA). If the initial EIA result is positive, the laboratory repeats the EIA on the same blood sample, and if the repeat result is positive, the remainder of the blood is used to perform a confirmatory test, either immunofluorescent antibody (IFA) or Western blot assay. Because children younger than 18 months may have a positive HIV antibody test result because of the presence of passively acquired maternal antibody, assays that directly detect HIV DNA or RNA (generically referred to as HIV nucleic acid amplification tests) are required for diagnosis of HIV infection in children younger than 18 months.[12,13] Results of conventional HIV antibody tests and HIV nucleic acid amplification tests usually require hours to days to be returned.

"Rapid" HIV antibody tests have been available since 2002.[3,5,14] These are screening tests, which means that a positive test result requires confirmation with an IFA or Western blot assay. The rapid antibody test is more sensitive and more specific than the conventional EIA, so a conventional EIA is not used as the confirmatory test for a rapid HIV antibody test.[15] In 1 study of the feasibility and benefit of use of the rapid test in pregnant women already in labor when they presented to health care professionals, the positive predictive value of the rapid test was shown to be higher than that of the conventional EIA.[4] That study of 4849 women (HIV prevalence: 7 in 1000) demonstrated that for the conventional EIA, the sensitivity was 100%, specificity was 99.8%, and the positive predictive value was 76%, whereas for the rapid HIV test, the sensitivity was 100%, specificity was 99.9%, and the positive predictive value was 90%.[4]

Although it is usually recommended that all HIV antibody screening tests be confirmed before HIV-specific treatments are started, this can take several weeks, because there is often a delay between availability of the results of the screening test and results of the confirmatory IFA or Western blot assay. This is not problematic for a woman identified early in pregnancy, because initiation of ARV prophylaxis against MTCT generally is not started until the second trimester. However, it is a problem for a woman who is late in pregnancy or in labor or is being tested immediately postpartum. In such instances, time is of the essence in initiating ARV prophylaxis to prevent MTCT. Therefore, when women have positive results of rapid antibody screening late in pregnancy, during labor, or within the first few hours of delivery of the infant, ARV prophylaxis to prevent MTCT should be instituted promptly on the basis of the positive results of the screening test. A maternal blood sample for a confirmatory HIV antibody assay should be obtained and sent for testing.[4,16,17] Prophylaxis should be stopped if the confirmatory test result is negative.

BENEFITS OF HIV TESTING

HIV testing during pregnancy allows identification of HIV infection in women who might not know they are infected. This is important for the health of the woman, because knowledge of her HIV-infection status will allow appropriate evaluation, including $CD4^+$ T-lymphocyte count and HIV viral load quantification, initiation of comprehensive care, and appropriate ARV treatment. HIV antibody testing early in pregnancy has the added benefit of allowing the most effective interventions to prevent MTCT of HIV to be initiated, including ARV prophylaxis, planning an appropriate mode of delivery (elective cesarean delivery or vaginal delivery, depending on maternal viral load near delivery), and avoidance of breastfeeding. HIV antibody testing later in pregnancy, or even after delivery of the newborn infant, still allows initiation of effective ARV interventions that can reduce the risk of MTCT of HIV.

Benefits of HIV Testing Early in Pregnancy

Single-Drug ARV Prophylaxis and MTCT of HIV

The 3-part 1994 Pediatric AIDS Clinical Trials Group study 076 (PACTG 076) regimen is the starting point for understanding ARV prophylaxis and the prevention of MTCT of HIV. Among nonbreastfeeding pregnant women with HIV infection and a $CD4^+$ T-lymphocyte count of greater than 200 cells per mm^3, oral zidovudine (ZDV) prophylaxis initiated after the first trimester, followed by administration of intravenous ZDV beginning at the onset of labor and continued until the cord is clamped, combined with 6 weeks of oral ZDV administered to the infant (2 mg/kg per dose every 6 hours), reduces the rate of MTCT of HIV from 25% to 8%.[18] Among nonbreastfeeding pregnant women with HIV infection, initiation of ZDV prophylaxis before the 28th week of pregnancy is associated with a lower risk of in utero transmission of HIV than is prophylaxis initiated at 35 weeks of pregnancy.[19]

Combination ARV Regimens and MTCT of HIV

Regimens that include combinations of 3 ARV drugs are more effective for prevention of MTCT of HIV than is

ZDV alone.[20,21] For nonbreastfeeding pregnant women with HIV infection, successful combination therapy with 3 ARV drugs and resultant reduction of maternal plasma virus load to below the limits of detection on sensitive assays (the goal of standard ARV therapy) is associated with rates of MTCT of HIV of less than 1%.[22–24] Current US Public Health Service (USPHS) guidelines for prevention of MTCT of HIV recommend use of combination ARV regimens including at least 3 ARV drugs during pregnancy and labor for all pregnant women with HIV infection. ARV drugs are discontinued after delivery unless the mother requires ARV therapy for her own health, in which case ARV therapy would be continued following guidelines for nonpregnant HIV-infected adults.[25,26] Intravenous ZDV should be administered to the pregnant woman during labor until the cord is clamped, with the other ARV drugs in the regimen continued orally during labor, and all infants should receive 6 weeks of ZDV prophylaxis.[25]

The full 6-week course of infant ARV prophylaxis, and careful instructions for its administration, should be provided to the family before discharge from the hospital. A prescription and recommendations to purchase ZDV for use by the infant are not adequate to ensure appropriate prophylaxis. In some states, infants may not be registered for insurance for a few weeks after birth, so even if the family has insurance, coverage may not be immediately available to pay for health care costs for the infant. Some families have health insurance that covers inpatient costs but not prescription medications. Outpatient pharmacies may not stock the infant-dosage form of ZDV. At hospital discharge, the family should be supplied with the medication itself, along with careful instructions for its administration, not just a prescription.

Mode of Delivery and MTCT of HIV

Elective cesarean delivery (performed before onset of labor and before rupture of membranes) can prevent MTCT of HIV[27] and is associated with at least a 50% decrease in the risk of MTCT among HIV-infected women either not receiving ARV drugs or receiving ZDV alone.[28] Although several studies have suggested that elective cesarean delivery performed before labor onset and before rupture of membranes may remain effective among HIV-infected women with low virus load (low either intrinsically off ARV therapy or low because of administration of combination ARV regimens during pregnancy), further research is required to definitively demonstrate whether elective cesarean delivery can further reduce the risk of MTCT of HIV for women being successfully treated with combinations of 3 or more ARV drugs (eg, virus load undetectable on sensitive assays while on a combination 3-drug ARV regimen).[29] Current American College of Obstetricians and Gynecologists (ACOG)[30] and USPHS guidelines for prevention of MTCT recommend elective cesarean delivery at 38 weeks' gestation for all HIV-infected pregnant women with HIV RNA levels greater than 1000 copies per mL near the time of delivery (or who have unknown viral load), regardless of the type of maternal ARV prophylaxis being received.[14,25]

Breastfeeding

Breastfeeding confers approximately 9% to 15% excess risk of MTCT of HIV. In the United States, because safe infant feeding alternatives exist, women with HIV infection should not breastfeed regardless of maternal ARV use.[31,32]

Benefits of HIV Testing in the Peripartum and Newborn Periods

When HIV antibody testing is performed before or during pregnancy, if a woman is found to be infected with HIV, it is possible to use all 3 known efficacious interventions for prevention of MTCT of HIV (prepartum and intrapartum maternal and postpartum infant ARV prophylaxis, elective cesarean delivery, and avoidance of breastfeeding). However, if HIV diagnostic testing is not performed until the peripartum or postpartum periods, then only 2 of the 3 interventions can be implemented (intrapartum maternal and postpartum infant ARV prophylaxis and avoidance of breastfeeding). Although ARV prophylaxis initiated during pregnancy is most effective at reducing MTCT of HIV, prophylaxis initiated for the pregnant woman at the time of labor and continued to the infant after birth, or even prophylaxis only administered to the infant after birth, can reduce the risk of MTCT of HIV compared with no prophylaxis.[6,7,10] Moreover, identification of HIV exposure allows the pediatrician to offer advice on appropriate alternatives to breastfeeding, follow-up testing, and prophylaxis against opportunistic infections for the infant as well as referral of the mother for care of her HIV infection.[12]

For the woman with HIV infection identified at the time of labor, maternal prophylaxis with intravenous ZDV, together with infant prophylaxis with 6 weeks of ZDV, is associated with an approximately 60% lower risk of MTCT of HIV[7] compared with no prophylaxis. For infants whose mothers received no ARV therapy during pregnancy or labor, prompt (optimally as soon as possible after birth but certainly within 12 hours after birth) prophylaxis of the infant with ZDV alone for 6 weeks is associated with a 50% reduction in the risk of MTCT of HIV compared with no prophylaxis.[7]

In certain situations, some experts combine the 6-week infant ZDV prophylaxis regimen with additional ARV drugs. Such situations might include infants born to mothers who received prenatal ARV drugs but had suboptimal viral suppression at delivery, particularly if the infant was delivered vaginally; infants born to mothers who have received only intrapartum ARV drugs; infants born to mothers who have received no prepartum or intrapartum ARV drugs; and infants born to mothers with known drug-resistant virus. Whether combining ZDV with other ARV drugs provides additional efficacy for prevention of MTCT of HIV has not been proven in clinical trials. In addition, appropriate ARV drug formulations and dosing regimens for neonates are incompletely defined for many drugs, and there are minimal data about the safety of combination ARV drugs in the neonate. Therefore, use of combination infant ARV prophylaxis involves complex balancing of potential benefits in terms of prevention of MTCT of HIV and risks in

terms of toxicity to the infant. The USPHS guidelines for prevention of MTCT of HIV include extensive discussion of considerations for infant ARV prophylaxis regimens for different clinical scenarios and should be reviewed for specific recommendations.[25] If infant prophylaxis with ARV drugs in addition to ZDV is being considered, decisions and choice of ARV drugs should be determined in consultation with a practitioner who is experienced in care of infants with HIV infection.

Other Considerations

Early identification of HIV-exposed infants allows (1) appropriate testing to identify HIV-infection status of the infant, (2) counseling of the mother regarding the risk of HIV transmission through breastfeeding and institution of appropriate infant feeding, and (3) prophylaxis with trimethoprim-sulfamethoxazole to prevent *Pneumocystis jiroveci* infection for infants whose HIV-infection status has not been determined or are identified as being HIV infected.[12]

SUMMARY: PROPHYLAXIS AND TREATMENT OF PREGNANT WOMEN WITH HIV INFECTION AND THEIR INFANTS

Guidelines for initiation of ARV therapy for pregnant women are the same as for nonpregnant HIV-infected adults and follow the USPHS "Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents"[26] except that the choice of ARV drugs includes special considerations related to pregnancy and fetal drug exposure as described in the "Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States."[25] For women who need immediate initiation of ARV therapy for their own health, treatment should be initiated as soon as possible, including in the first trimester. For women who do not require treatment for their own health, the effectiveness of ARV prophylaxis depends on the timing of institution of such prophylaxis. For women identified as being HIV infected early in pregnancy, generally 3 ARV drugs are recommended for prophylaxis during their pregnancy and should be continued until the time of delivery. Delaying initiation of prophylaxis until after the first trimester can be considered if treatment of HIV infection is not needed for the woman's own health, intravenous ZDV is administered to the pregnant woman at the time of labor and continued until the cord is clamped, and the other ARV components of the regimen are continued orally during labor. Oral ZDV is administered to the infant for the first 6 weeks of life.[25] For women identified as being HIV infected during labor, intravenous ZDV is recommended together with infant ARV prophylaxis. For infants born to women who have not received prepartum or intrapartum ARV therapy, prophylaxis of the infant with 6 weeks of ZDV is recommended. In the latter 2 situations, some experts may administer additional ARV drugs to the mother and/or infant. The USPHS guidelines for prevention of MTCT of HIV should be consulted for detailed discussion of these more complex situations, and decisions for maternal and infant prophylaxis and therapy in such situations should be made in consultation with a practitioner who is experienced in care of infants with HIV infection.[25]

RISKS OF HIV TESTING IN THE PRENATAL AND NEWBORN PERIODS

A positive HIV antibody test result for an infant identifies HIV infection in the mother and HIV exposure (with possible infection) of the infant. Therefore, even if testing is only performed on the infant after birth, if the infant is found to be HIV-seropositive, the infant's mother will be identified as having HIV infection, which can be associated with personal psychological trauma and societal stigma if the mother does not know that she is infected. Linkage of the newly identified HIV-infected mother to appropriate psychosocial supports and to HIV care programs is important. If the test result is found to be a false-positive, this psychological harm will have occurred needlessly. Thus, the fact that confirmatory testing is required to definitively diagnose HIV infection of the mother, and the need for rapid presumptive treatment of the infant to prevent MTCT should she be HIV infected, should be explained to the mother when performing rapid testing during labor or after delivery. ARV administration to the mother and/or infant may be associated with infant drug toxicity,[33–35] and if the rapid test result is not confirmed to be positive, the benefit/risk ratio may not favor prophylaxis. However, the infant should have received only 1 to 2 days of ARV prophylaxis in such a situation, and short-term toxicity of ARV drugs is limited. Expedited confirmatory testing should be performed to ensure that results are reported quickly so that the duration of infant exposure to ARV drugs is minimized.

CONSENT FOR HIV TESTING

Opt-out consent (documented patient notification, with testing to take place unless rejected by the patient) is associated with higher testing percentages than opt-in consent,[36–38] and universal HIV screening of pregnant women with opt-out consent is recommended by the CDC,[11] the ACOG,[14] and the AAP.[39] As part of its recommendation, the CDC states that HIV screening should be included in the routine panel of prenatal screening tests for all pregnant women and that separate written consent for HIV testing should not be required. The CDC also states that general consent for medical care should be considered sufficient to encompass consent for HIV care.[11] In states where laws or regulations require written informed maternal consent for testing ("opt-in" consent), practitioners should obtain appropriate consent as required. A compendium of state HIV-testing laws can be found at www.ucsf.edu/hivcntr.

In states where laws and regulations require written informed maternal consent for testing, practitioners should work to modify the laws or regulations to permit opt-out consent. Such an advocacy effort is best undertaken with a broad coalition of interested parties throughout the state, including state and local health departments, the state AAP chapter, representatives of the ACOG and the American Academy of Family Physi-

cians, nursing groups, community groups interested in maternal health, and AIDS activist organizations.

Mandatory HIV testing of the newborn infant whose mother has not been tested during pregnancy or in the immediate postpartum period has been associated with high rates of prenatal testing in New York state[7] and may act as a safety net for identifying infants who would not have been tested otherwise. There has not been a study to compare the percentage of women tested before delivery in programs with mandatory newborn testing compared with those with opt-out consent policies. Therefore, an evidence-based recommendation for or against mandatory newborn testing cannot be made. A few states have passed laws that require HIV testing of newborn infants without maternal consent when the HIV-infection status of the mother is unknown. In states where legislation aimed at mandating testing of newborn infants has been proposed, issues have been raised regarding the ethics and legality of this approach, because it diagnoses HIV infection in the mother without her consent for testing. In addition, concerns have been raised about the costs of such screening programs, given the already high numbers of mothers and newborn infants tested in voluntary (opt-out) programs. Regardless of the form of consent used in testing programs, it is important that the results of infant testing be returned as rapidly as possible so that ARV prophylaxis for the infant can be started promptly if needed. Infant ARV prophylaxis is likely to be less effective in the prevention of MTCT of HIV when started later than 12 hours after birth. Optimal prevention of MTCT of HIV requires identification of the mother's HIV status during pregnancy.

TIMING OF TESTING IN PREGNANCY

As noted, testing of the pregnant woman early in pregnancy is recommended to allow informed and timely therapeutic decisions concerning health care for her and for prevention of MTCT of HIV.[11] A second HIV test during the third trimester has been shown to be cost-effective under certain conditions,[40] and the CDC recommends that a second test be performed late in pregnancy but at <36 weeks' gestation for women who are in areas of high incidence, for women delivering in hospitals with HIV prevalence in pregnant women of at least 1 in 1000, and for women at high risk of acquiring HIV (women with a sexually transmitted infection diagnosed during pregnancy, injection drug users and their partners, women who exchange sex or money for drugs, women who are sex partners of HIV-infected persons, women who have had a new or more than 1 sex partner during pregnancy, or women with signs/symptoms of acute HIV infection).[11] However, because risk-based and prevalence-based testing programs may be difficult to implement, some practitioners and hospitals choose to test all pregnant women a second time late in pregnancy, even in the absence of specific prevalence or risk data. Because of the high levels of viral replication observed with acute HIV infection, women who become infected with HIV during pregnancy have a particularly high risk of transmitting HIV to their infants. For women whose HIV status is unknown at the time of presentation in labor, testing should be timed so that results are available to allow predelivery administration of prophylaxis if indicated. For a newborn infant whose mother's HIV status is unknown, testing should be performed quickly enough so that results can be available for infant ARV prophylaxis to begin within 12 hours of birth, as stated previously.[11]

CONCLUSIONS

Universal HIV testing of pregnant women is standard care in the United States. Identification of HIV infection early in pregnancy allows the greatest ability to treat the pregnant woman for her HIV infection for her own health and to prevent MTCT of HIV. Rapid HIV antibody testing allows for timely identification of HIV infection in women even late in pregnancy, during labor, or in the immediate postpartum period as well as HIV exposure in their newborn infants. The results can be available quickly enough to implement successful ARV interventions that can reduce MTCT of HIV when administered to the mother started later in pregnancy or in labor or to the infant when administered within the first few hours of life.

RECOMMENDATIONS

1. Information about HIV infection, prevention of MTCT of HIV, and HIV antibody testing should be provided routinely as part of a comprehensive program of health care for pregnant women.
2. Documented, routine HIV antibody testing should be performed for all pregnant women in the United States after notifying the patient that testing will be performed, unless the patient declines HIV testing (opt-out consent or right of refusal). All HIV antibody testing should be performed in a manner consistent with state and local laws.
3. In states where laws and regulations require written informed maternal consent for testing, health care professionals should work to modify the laws or regulations to permit opt-out consent.
4. All programs for the detection of HIV infection in pregnant women and their infants should periodically evaluate the proportion of women who are not tested. Programs in which an unacceptably high proportion of women do not receive HIV antibody testing should examine the reasons and make appropriate program modifications as needed.
5. Repeat HIV antibody testing is recommended in the third trimester, preferably before 36 weeks' gestation, for women in states with high HIV prevalence in women 15 to 45 years of age, for women delivering in hospitals with HIV prevalence of 1 or more in 1000 pregnant women screened, or for women at increased risk of acquiring HIV (women with a sexually transmitted infection diagnosed during pregnancy, injection drug users and their partners, women who exchange sex or money for drugs, women who are sex partners of HIV-infected per-

sons, women who have had a new or more than 1 sex partner during pregnancy, or women with signs/symptoms of acute HIV infection). Because prevalence-based testing may be difficult to implement and individual risk assessment is unreliable and the risk of MTCT of HIV is high in women who first acquire HIV infection during pregnancy, some experts recommend that repeat HIV screening be considered for all pregnant women in the third trimester.

6. For women in labor with undocumented HIV-infection status during the current pregnancy, maternal HIV antibody testing with opt-out consent, using a rapid HIV antibody test, is recommended. For women with a positive HIV rapid antibody test result, ARV prophylaxis should be administered to the mother and newborn infant on the basis of the positive rapid antibody test result without waiting for results of confirmatory HIV testing, and breastfeeding should not occur. Assistance with the immediate initiation of hand and pump expression to stimulate milk production should be offered to the mother, given the possibility that the confirmatory test results may be negative. If confirmatory test results are negative, prophylaxis should be stopped and breastfeeding may be initiated.
7. Rapid HIV antibody testing should be available on a 24-hour basis at all facilities with an obstetric unit and/or newborn nursery of any level.
8. The health care professional for the newborn infant needs to be informed promptly of maternal HIV serostatus so that appropriate care and testing of the newborn infant can be accomplished and so that ARV prophylaxis can be administered to HIV-exposed infants. The infant medical chart needs to contain documentation of the maternal HIV-infection status. Presence of maternal HIV-infection status on the maternal and infant record should be a standard measure of the adequacy of hospital care for the mother and infant.
9. For newborn infants whose mother's HIV serostatus is unknown, the newborn infant's health care professional should order rapid HIV antibody testing to be performed for the mother or the newborn, with appropriate consent as required by state or local law. Results should be reported to health care professionals quickly enough to allow effective ARV prophylaxis to be administered, if indicated, to the infant as soon as possible after birth but certainly by 12 hours after birth. ARV prophylaxis for the newborn infant should be administered promptly on the basis of a positive rapid antibody test result without waiting for results of confirmatory HIV testing. Breastfeeding should be avoided. Confirmatory testing should be performed, and assistance with hand and pump expression to stimulate milk production should be offered to the mother, given the possibility that the confirmatory test results may be negative. If confirmatory test results are negative (indicating that the infant was not truly exposed to HIV), then ARV prophylaxis should be stopped and breastfeeding may be initiated. If the confirmatory test result is positive, infants should receive ARV prophylaxis for 6 weeks after birth, and they should not breastfeed. Prophylaxis is most effective if administered within 12 hours of birth but may still be effective when administered as late as at 48 hours of life.
10. The full 6-week course of infant ARV prophylaxis, and careful instructions for its administration, should be provided to the family before discharge from the hospital. Payment for this should be covered by all third-party payers.
11. If the mother or infant has a positive test result for HIV antibody, the infant should not breastfeed.
12. In the absence of parental availability for consent to test the newborn infant for HIV antibody, the newborn infant should be tested, ideally within the first 12 hours of life. State and local jurisdictions need to develop procedures to facilitate the rapid evaluation and testing of the infant.
13. For infants of unknown HIV exposure status at the first health supervision visit, HIV antibody testing with appropriate consent should be performed to guide appropriate care and follow-up testing if needed.
14. Care of the mother, fetus, newborn, and child with perinatal exposure to HIV should be performed in consultation with specialists in obstetric and pediatric HIV infection.

*Lead authors.

REFERENCES

1. Centers for Disease Control and Prevention. *Enhanced Perinatal Surveillance: United States, 1999–2001*. Atlanta, GA: US Depart-

ment of Health and Human Services; 2004. Available at: www.cdc.gov/hiv/topics/surveillance/resources/reports/2004spec_no4/pdf/SpecialReport10-7.pdf. Accessed February 27, 2008
2. Mofenson LM; American Academy of Pediatrics, Committee on Pediatric AIDS. Technical report: perinatal human immunodeficiency virus testing and prevention of transmission. *Pediatrics.* 2000;106(6). Available at: www.pediatrics.org/cgi/content/full/106/6/e88
3. Keenan PA, Keenan JM, Branson BM. Rapid HIV testing: wait time reduced from days to minutes. *Postgrad Med.* 2005;117(3):47–52
4. Bulterys M, Jamieson DJ, O'Sullivan MJ, et al. Rapid HIV-1 testing during labor: a multicenter study. *JAMA.* 2004;292(2):219–223
5. Greenwald JL, Burstein GR, Pincus J, Branson B. A rapid review of rapid HIV antibody tests. *Curr Infect Dis Rep.* 2006;8(2):125–131
6. Wade NA, Birkhead GS, Warren BL, et al. Abbreviated regimens of zidovudine prophylaxis and perinatal transmission of the human immunodeficiency virus. *N Engl J Med.* 1998;339(20):1409–1414
7. Wade NA, Zielinski MA, Butsashvili M, et al. Decline in perinatal HIV transmission in New York State (1997–2000). *J Acquir Immune Defic Syndr.* 2004;36(5):1075–1082
8. Gray GE, Urban M, Chersich MF, et al. A randomized trial of two postexposure prophylaxis regimens to reduce mother-to-child HIV-1 transmission in infants of untreated mothers. *AIDS.* 2005;19(12):1289–1297
9. Taha TE, Kumwenda NI, Gibbons A, et al. Short postexposure prophylaxis in newborn babies to reduce mother-to-child transmission of HIV-1: NVAZ randomised clinical trial. *Lancet.* 2003;362(9391):1171–1177
10. Fiscus SA, Schoenbach VJ, Wilfert C. Short courses of zidovudine and perinatal transmission of HIV. *N Engl J Med.* 1999;340(13):1040–1041; author reply 1042–1043
11. Branson BM, Handsfield HH, Lampe MA, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *MMWR Recomm Rep.* 2006;55(RR-14):1–17
12. Havens PL, Mofenson LM, American Academy of Pediatrics, Committee on Pediatric AIDS. Evaluation and management of the infant exposed to human immunodeficiency virus type 1 in the United States. *Pediatrics.* 2009; in press
13. Read JS; American Academy of Pediatrics, Committee on Pediatric AIDS. Diagnosis of HIV-1 infection in children younger than 18 months in the United States. *Pediatrics.* 2007;120(6). Available at: www.pediatrics.org/cgi/content/full/120/6/e1547
14. American College of Obstetricians and Gynecologists, Committee on Obstetric Practice. ACOG committee opinion number 304, November 2004: prenatal and perinatal human immunodeficiency virus testing: expanded recommendations. *Obstet Gynecol.* 2004;104(5 pt 1):1119–1124
15. Drociuk D, Gibson J, Hodge J Jr. Protocols for confirmation of reactive rapid HIV tests. *MMWR Morb Mortal Wkly Rep.* 2004;53(10):221–222
16. Centers for Disease Control and Prevention. Rapid point-of-care testing for HIV-1 during labor and delivery: Chicago, Illinois, 2002. *MMWR Morb Mortal Wkly Rep.* 2003;52(36):866–868
17. Centers for Disease Control and Prevention. Rapid HIV-1 antibody testing during labor and delivery for women of unknown HIV status: a practical guide and model protocol. Available at: www.cdc.gov/hiv/topics/testing/resources/guidelines/rt-labor&delivery_part4.htm. Accessed February 27, 2008
18. Connor EM, Sperling RS, Gelber R, et al. Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. Pediatric AIDS Clinical Trials Group Protocol 076 Study Group. *N Engl J Med.* 1994;331(18):1173–1180
19. Lallemant M, Jourdain G, Le Coeur S, et al. A trial of shortened zidovudine regimens to prevent mother-to-child transmission of human immunodeficiency virus type 1. Perinatal HIV Prevention Trial (Thailand) Investigators. *N Engl J Med.* 2000;343(14):982–991
20. Mandelbrot L, Landreau-Mascaro A, Rekacewicz C, et al. Lamivudine-zidovudine combination for prevention of maternal-infant transmission of HIV-1. *JAMA.* 2001;285(16):2083–2093
21. Leroy V, Sakarovitch C, Cortina-Borja M, et al. Is there a difference in the efficacy of peripartum antiretroviral regimens in reducing mother-to-child transmission of HIV in Africa? *AIDS.* 2005;19(16):1865–1875
22. Cooper ER, Charurat M, Mofenson L, et al. Combination antiretroviral strategies for the treatment of pregnant HIV-1-infected women and prevention of perinatal HIV-1 transmission. *J Acquir Immune Defic Syndr.* 2002;29(5):484–494
23. European Collaborative Study. Mother-to-child transmission of HIV infection in the era of highly active antiretroviral therapy. *Clin Infect Dis.* 2005;40(3):458–465
24. Stringer JS, Rouse DJ, Goldenberg RL. Prophylactic cesarean delivery for the prevention of perinatal human immunodeficiency virus transmission: the case for restraint. *JAMA.* 1999;281(20):1946–1949
25. Perinatal HIV Guidelines Working Group. *Public Health Service Task Force Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States.* Rockville, MD: AIDSInfo, US Department of Health and Human Services; 2007:1–96. Available at: http://aidsinfo.nih.gov/ContentFiles/PerinatalGL.pdf. Accessed November 5, 2007
26. Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents.* Rockville, MD: US Department of Health and Human Services; 2008:1–128. Available at: www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Accessed February 27, 2007
27. European Mode of Delivery Collaboration. Elective caesarean-section versus vaginal delivery in prevention of vertical HIV-1 transmission: a randomised clinical trial [published correction appears in *Lancet.* 1999;353(9165):1714]. *Lancet.* 1999;353(9158):1035–1039
28. International Perinatal HIV Group. The mode of delivery and the risk of vertical transmission of human immunodeficiency virus type 1: a meta-analysis of 15 prospective cohort studies. *N Engl J Med.* 1999;340(13):977–987
29. Read JS, Newell MK. Efficacy and safety of cesarean delivery for prevention of mother-to-child transmission of HIV-1. *Cochrane Database Syst Rev.* 2005;(4):CD005479
30. American College of Obstetricians and Gynecologists, Committee on Obstetric Practice. ACOG committee opinion scheduled Cesarean delivery and the prevention of vertical transmission of HIV infection. Number 234, May 2000 (replaces number 219, August 1999). *Int J Gynaecol Obstet.* 2001;73(3):279–281
31. Coutsoudis A, Dabis F, Fawzi W, et al. Late postnatal transmission of HIV-1 in breast-fed children: an individual patient data meta-analysis. Breastfeeding and HIV International Study Group. *J Infect Dis.* 2004;189(12):2154–2166
32. Read JS; American Academy of Pediatrics, Committee on Pediatric AIDS. Human milk, breastfeeding, and transmission of human immunodeficiency virus type 1 in the United States. *Pediatrics.* 2003;112(5):1196–1205
33. Divi RL, Walker VE, Wade NA, et al. Mitochondrial damage and DNA depletion in cord blood and umbilical cord from infants exposed in utero to Combivir. *AIDS.* 2004;18(7):1013–1021

34. Briand N, Le Coeur S, Traisathit P, et al. Growth of human immunodeficiency virus-uninfected children exposed to perinatal zidovudine for the prevention of mother-to-child human immunodeficiency virus transmission. *Pediatr Infect Dis J.* 2006; 25(4):325–332
35. Pacheco SE, McIntosh K, Lu M, et al. Effect of perinatal antiretroviral drug exposure on hematologic values in HIV-uninfected children: an analysis of the women and infants transmission study. *J Infect Dis.* 2006;194(8):1089–1097
36. Stringer EM, Stringer JS, Cliver SP, Goldenberg RL, Goepfert AR. Evaluation of a new testing policy for human immunodeficiency virus to improve screening rates. *Obstet Gynecol.* 2001; 98(6):1104–1108
37. Centers for Disease Control and Prevention. HIV testing among pregnant women: United States and Canada, 1998–2001. *MMWR Morb Mortal Wkly Rep.* 2002;51(45):1013–1016
38. Moses A, Zimba C, Kamanga E, et al. Prevention of mother-to-child transmission: program changes and the effect on uptake of the HIVNET 012 regimen in Malawi. *AIDS.* 2008;22(1):83–87
39. American Academy of Pediatrics; American College of Obstetricians and Gynecologists. Human immunodeficiency virus screening. *Pediatrics.* 1999;104(1 pt 1):128
40. Sansom SL, Jamieson DJ, Farnham PG, Bulterys M, Fowler MG. Human immunodeficiency virus retesting during pregnancy: costs and effectiveness in preventing perinatal transmission. *Obstet Gynecol.* 2003;102(4):782–790

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