

# Iowa's Perinatal Guidelines for HIV



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## PREFACE

his document represents Appendix O in the Eighth Edition of *Guidelines for Perinatal Services*. These guidelines are not meant to hold Iowa hospitals and Iowa perinatal professionals to an impractical ideal but to provide guidance on

recommendations and state requirements, when applicable, for delivery of perinatal services.

Appendix O: Pregnancy and HIV (Human Immunodeficiency Virus) was approved by the Perinatal Guidelines Advisory Committee on June 15, 2007.

When they are complete, the *Guidelines for Perinatal Services* will be posted in its entirety on Iowa's Statewide Perinatal Care Program's website at: <u>http://www.idph.state.ia.us/hpcdp/statewide\_perinatal\_care.asp</u>

Comments or questions regarding *Guidelines for Perinatal Services*, 2007 may be addressed to:

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### **O. Pregnancy and HIV (Human Immunodeficiency Virus)**

Since 1994, the United States Public Health Service has recommended universal, voluntary testing of pregnant women. The decrease in mother-to-child (perinatal) HIV transmission is a public health achievement in HIV prevention in the United States. Nationally, the number of infants infected with HIV through perinatal transmission has decreased from 1,650 during the early- to mid-1990s to fewer than 240 in 2002. This decline is attributed to multiple interventions, including routine, voluntary HIV testing of pregnant women, the use of rapid HIV tests at delivery for women of unknown HIV status, and the use of antiretroviral therapy by HIV-infected women during pregnancy and by infants after birth.

While the need for pregnant women to know their HIV status was recognized early in the epidemic as a key step to preventing perinatal transmission, testing efforts to date have often focused on risk-based screening or voluntary, opt-in systems of testing. These types of systems have been shown to be only moderately successful at achieving testing of pregnant women, in part because they depend on the ability of a health care provider to discern potential risk behaviors and on the enthusiasm with which the provider recommends the testing.<sup>1</sup>

Beginning in 1998, health care providers in Iowa were required to offer HIV testing to pregnant women who met certain risk criteria. The Iowa Barriers to Prenatal Care Project surveys women who give birth in Iowa hospitals. In 2005, over 18,000 women returned surveys. Approximately 68% of women remembered being offered an HIV test but only 47% received the test. This low rate of testing may have contributed to a higher than expected number of HIV-infected infants in Iowa. Between 2000 and 2005, 46 infants were born to HIV-positive mothers in Iowa. Of these 46 infants, three (7%) became infected with HIV, well above the 2% expected when appropriate and timely interventions are accessed.

In September 2006, the Centers for Disease Control and Prevention (CDC) released the *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings* (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm). These new recommendations, which replace CDC's 1993 *Recommendations for HIV Testing Services for Inpatients and Outpatients in Acute-Care Hospital Settings*, advise universal, opt-out testing for pregnant women. CDC's recommendations include the following:

- All pregnant women in the United States should be screened for HIV infection.
- Health care providers should test women for HIV as early as possible in the pregnancy.

<sup>&</sup>lt;sup>1</sup> Royce RA, Walter EB, Fernandez MI, Wilson TE, Ickovics JR, Simonds RJ. Barriers to universal prenatal HIV testing in 4 US locations in 1997. Am J Public Health 2001;91:727-33.

- Screening should occur after the patient is notified that:
  (a) HIV screening is recommended for all pregnant patients; and
  (b) She will receive an HIV test as part of the routine panel of prenatal blood tests, unless she declines (i.e., opt-out screening).
- HIV testing must be voluntary and free of coercion.
- Pregnant women should receive oral or written information that includes an explanation of HIV infection, a description of interventions that can reduce HIV transmission from mother to infant, and the meanings of positive and negative results.
- No additional process or written documentation of informed consent should be required for HIV tests beyond that for other routine prenatal tests.
- Pregnant women should be given the opportunity to ask questions and to decline testing. If a patient declines testing, this decision should be documented in the medical record.
- Health care providers should discuss and address reasons for declining an HIV test (e.g., lack of perceived risk, fear of the disease, and concerns regarding partner violence or potential stigma or discrimination).
- Women who decline the test early in prenatal care should be encouraged to be tested at a subsequent visit.
- A second HIV test during the third trimester, preferable <36 weeks of gestation may be considered for all pregnant women, and is recommended for women with risk factors (e.g., injection drug users and their sex partners, women who exchange sex for money or drugs, women who are sex partners of HIV-infected persons, and women who have had a new or more than one sex partner during this pregnancy) or who have signs or symptoms consistent with acute HIV infection.
- Any woman with an undocumented HIV status at the time of labor should be screened with a rapid HIV test unless she declines (opt-out screening).
- When a woman's HIV status is still unknown at time of delivery, she should be screened immediately postpartum with a rapid HIV test unless she declines (opt-out screening).
- Immediate initiation of appropriate antiretroviral prophylaxis should be recommended to women on the basis of a reactive rapid test result without waiting for the result of a confirmatory test.
- When the mother's HIV status is unknown postpartum, rapid testing of the newborn as soon as possible after birth is recommended so antiretroviral prophylaxis can be offered to HIV-exposed infants. Women should be informed that identifying HIV antibodies in the newborn indicates that the mother is infected.

#### IOWA REQUIREMENTS AND GUIDELINES FOR HIV TESTING DURING PREGNANCY

*Iowa Code Chapter 141A* governs HIV testing. On July 1, 2007, new provisions took effect. The following requirements and guidelines are consistent with Iowa Code. Requirements of Iowa Code are indicated by a code citation following the entry.

#### A. Pretest Education

#### Required:

- Information about HIV prevention, risk reduction, and treatment opportunities to reduce the possible transmission of HIV to a fetus shall be made available to all pregnant women. (141A.4)
- Prior to undergoing an HIV test, information shall be available concerning testing and how to obtain additional information about HIV infection and risk reduction. (141A.6)

#### Recommended:

- All health care providers of pregnant women should be knowledgeable about HIV in pregnancy, the treatment needed to protect infants of HIV-positive mothers, how to discuss HIV and risk factors with patients, and how to refer HIV-positive and high-risk patients for other support services.
- All pregnant women should receive the required information as early as possible during the prenatal period.
- The opportunity for the woman to ask questions about HIV should be provided in a supportive manner by the health care provider.

#### **B.** Consent

All pregnant women must be tested for HIV, unless they decline (141A.4). For pregnant *adult* women, no further consent is required; only refusals must be obtained and documented.

#### Required:

Minors have the legal capacity to act and give consent for the diagnosis and treatment of sexually transmitted diseases without the consent of a parent or guardian (139A.35). However, written consent from the minor is required for an HIV test:

• <u>Minors</u>. Prior to testing, a minor patient shall be informed that upon confirmation of a positive test result, the minor's legal guardian is required to be informed of the result. Testing facilities where minors are tested shall have available a program to assist minors and legal guardians with the notification process, emphasizing the need for family support and making resources available to accomplish that goal. Minors

must give written consent to these procedures *and* to receiving services, screening, or treatment. (141A.7)

#### C. Testing

#### Required:

- All pregnant women shall be tested for HIV infection as part of the routine panel of prenatal tests. (141A.4)
- A pregnant woman shall be notified that HIV screening is recommended for all prenatal patients and that the pregnant woman will receive an HIV test as part of the routine panel of prenatal tests unless she objects to the test. (141A.4)
- If a pregnant woman objects to and declines the test, the decision shall be documented in her medical record. (141A.4)

#### Recommended:

- Testing should occur as early in the pregnancy as possible.
- Health care providers should discuss and address reasons for declining an HIV test (e.g., lack of perceived risk, fear of the disease, and concerns regarding partner violence or potential stigma or discrimination), and encourage women who decline the test early in prenatal care to be tested at a subsequent visit.
- A second HIV test during the third trimester, preferable <36 weeks of gestation may be considered for women with risk factors (e.g., injection drug users and their sex partners, women who exchange sex for money or drugs, women who are sex partners of HIV-infected persons, and women who have had a new or more than one sex partner during this pregnancy) or who have signs or symptoms consistent with acute HIV infection.

#### **D.** Post-test Counseling

#### Required:

Post-test counseling is required only if the test is positive.

• At any time that the subject of an HIV test is informed of confirmed positive test results, counseling concerning the emotional and physical health effects shall be initiated. Particular attention shall be given to explaining the need for the precautions necessary to avoid transmitting the virus. The subject shall be given information concerning additional counseling. (141A.7)

#### Recommended:

- The HIV-positive patient should be referred to an HIV specialist for follow up.
- Partner notification should be explained to the patient at this time. Newly diagnosed persons will be contacted by a state or local health department disease prevention specialist to assist them in notifying partners who may also be infected with HIV.

#### E. Testing of the Newborn When the Mother's HIV Status is Unknown

#### Not Consistent with Iowa Code:

CDC recommends HIV testing of newborns immediately after birth when the HIV status of the mother has not been determined. However, testing of a newborn without the consent of a legal guardian is not consistent with Iowa Code 141A.6 unless the legal guardian cannot be located or is unavailable and the test results are necessary for diagnostic purposes to provide appropriate urgent medical care.

### GENERAL PRINCIPLES REGARDING TREATMENT RECOMMENDATIONS

Before prescribing any regimen:

- Discuss with HIV-infected patient the risks and benefits of antepartum, intrapartum, and postpartum use of zidovudine (ZDV) and the possibility of combination antiretroviral (ARV) therapy to reduce the risk of maternal-child HIV transmission;
- Address patient concerns;
- Obtain ZDV and other ARV use history; and
- Obtain HIV-1 RNA viral load and CD4+ count.

The Public Health Service Task Force issued revised *Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States* on October 12, 2006. It is emphasized that concepts relevant to HIV management evolve rapidly. The Task Force has a mechanism to update recommendations on a regular basis, and the most recent information is available on the AIDSinfo Web site (<u>http://AIDSinfo.nih.gov</u>).

Considerations related to counseling of the HIV-1 infected pregnant woman regarding risks for vertical transmission of HIV-1 to the fetus/neonate and to the obstetric care of such women include the following:

#### A. HIV-related Treatment

- Efforts to maximize the health of the pregnant woman, including the provision of highly active combination antiretroviral therapy, can be expected to correlate with both reduction in viral load and low rates of vertical transmission. At a minimum for the reduction of perinatal HIV-1 transmission, ZDV prophylaxis according to the Pediatric AIDS Clinical Trials Group (PACTG) 076 regimen is recommended unless the woman is intolerant of ZDV.
- Plasma HIV-1 RNA levels should be monitored during pregnancy according to the guidelines for management of HIV-1 infected adults. The most recently determined viral load value should be used when counseling a woman regarding mode of delivery.

#### **B.** Mode of Delivery

- Perinatal HIV-1 transmission is reduced by scheduled cesarean delivery among women with unknown HIV-1 RNA levels who are not receiving antiretroviral therapy or are receiving only ZDV for prophylaxis of perinatal transmission. Plasma HIV-1 RNA levels were not available in these studies to assess the potential benefit among women with low plasma HIV-1 RNA levels.
- Women with HIV-1 RNA levels > 1,000 copies/mL should be counseled regarding the potential benefit of scheduled cesarean delivery in reducing the risk of vertical transmission. The benefit among women on HAART is unproven.
- Data are insufficient to evaluate the potential benefit of cesarean delivery for neonates of antiretroviral-treated women with plasma HIV-1 RNA levels below1,000 copies/mL. Given the low rate of transmission among this group, it is unlikely that scheduled cesarean delivery would confer additional benefit in reduction of transmission.
- Management of women originally scheduled for cesarean delivery who present with ruptured membranes or in labor must be individualized based on duration of rupture, progress of labor, plasma HIV-1 RNA level, current antiretroviral therapy, and other clinical factors. It is not clear that cesarean delivery after rupture or onset of labor provides benefit in reducing transmission.
- Women should be informed of the risks associated with cesarean delivery; these risks to the woman should be balanced with potential benefits expected for the neonate.
- Women should be counseled regarding the limitations of the current data. The woman's autonomy to make an informed decision regarding route of delivery should be respected and honored.

#### C. HIV Drug Resistance

- HIV drug resistance testing is recommended for:
  - All pregnant women not currently receiving antiretrovirals, before starting treatment or prophylaxis.
  - All pregnant women receiving antenatal antiretroviral therapy who have virologic failure with persistently detectable HIV RNA levels or who have sub-optimal viral suppression after initiation of antiretroviral therapy.
- For optimal prevention of perinatal transmission, empiric initiation of antiretroviral therapy before results of resistance testing are available may be warranted, with adjustment as needed after the results are available.

- The use of highly active antiretroviral combination therapy to maximally suppress viral replication during pregnancy is the most effective strategy to prevent the development of resistance and to minimize the risk of perinatal transmission.
- All pregnant women should be counseled about the importance of adherence to prescribed antiretroviral medications to reduce the potential for development of resistance.

#### **D.** Use of Nevirapine during Pregnancy

- The addition of single-dose maternal/infant nevirapine (NVP) to an ongoing highly active combination antiretroviral therapy regimen does not provide additional efficacy in reducing perinatal transmission and may result in NVP drug resistance in the mother, and is therefore not recommended.
- NVP-based combination therapy should not be initiated in women with CD4+ count >250 cells/mm<sup>3</sup> unless the benefit clearly outweighs the risk due to concern about increased risk of hepatic toxicity. However, some pregnant women may receive an NVP-based combination antiretroviral therapy regimen for prophylaxis only, with plans to discontinue therapy after delivery. In this situation, consideration should be given to continuing the nucleoside analogue agents for 3-7 days after stopping NVP to minimize the risk of NVP resistance.

#### E. ARV Use during Labor and Delivery

• Women who have documented ZDV resistance and are on regimens that do not include ZDV for their own health should still receive intravenous ZDV during labor whenever possible, along with their established antiretroviral regimens, and oral ZDV for their infants according to the PACTG 076 protocol. For women who are receiving a stavudine-containing regimen, stavudine should be discontinued during labor while intravenous ZDV is being administered.

#### F. Prophylaxis for Newborn

• The optimal prophylactic regimen for newborns of women with antiretroviral (ARV) resistance is unknown. Therefore, ARV prophylaxis for an infant born to a woman with known or suspected drug resistance should be determined in consultation with a pediatric HIV specialist, preferably before delivery.

#### RESOURCES

**Iowa Department of Public Health** HIV/AIDS/Hepatitis Program (515) 242-5150 HIV Partner Notification Assistance Program (515) 242-5141

For questions regarding the clinical management of HIV/AIDS, contact: National HIV Telephone Consultation Service (800) 933-3413 http://www.ucsf.edu/hivcntr

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