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Reducing the Risk of Perinatal HIV Transmission in New Jersey and the U.S.: Legal and Clinical Strategies

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Learning Objectives

By the end of this activity participants will be able to:

1. Recognize the implications of New Jersey’s 2007 legislation on HIV testing in pregnancy to reduce perinatal HIV transmission.
2. Identify the 2011 updates to the Perinatal Guidelines that will have an impact on current practice.
3. Describe research findings that influence the 2011 Perinatal Guidelines update.

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Statement of Need:
This article reviews New Jersey state legislation on HIV testing in pregnancy and implementation of the law. The second section of the article provides an update on the U.S. Department of Health and Human Services Guidelines for women living with HIV who are pregnant or who are considering pregnancy.

This article aims to respond to questions and confusions amongst healthcare professionals regarding the requirements of the New Jersey legislation on HIV testing in pregnancy, with an emphasis on testing during labor and infant testing. The implementation of New Jersey’s 2007 legislation (NJ PL. 2007 c.218) regarding HIV testing in pregnancy has had an impact on both health professionals caring for pregnant women and women in care. Under the 2007 legislation HIV testing is included in routine prenatal testing using an “opt-out” approach. That is, the HIV test is conducted routinely, along with the standard battery of prenatal blood tests, unless the woman declines.

Medical management of pregnant women and pregnant women with HIV infection is rapidly evolving. The Perinatal Guidelines are updated at least annually and were most recently released on September 14, 2011. This article provides the reader with a summary of the key changes in the 2011 Perinatal Guidelines. As they are evidence based, the 2011 Perinatal Guidelines update includes an extensive review of the existing and newly reported clinical trial results that informed the authoring Panel’s recommendations. This article provides an overview of some of the key trials cited in the 2011 update, to support physician use of evidence based medicine.

Learning Objectives:
Following completion of this activity, participants should be able to:
1. Recognize the implications of New Jersey’s 2007 legislation on HIV testing in pregnancy to reduce perinatal HIV transmission.
2. Identify the 2011 updates to the Perinatal Guidelines that will have an impact on current practice.
3. Describe research findings that influence the 2011 Perinatal Guidelines update.

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Reduction of the Risk of Perinatal HIV Transmission
in New Jersey and the U.S.: Legal and Clinical Strategies

Introduction While the number of new cases of HIV infection in adults has
remained stubbornly high, the number of cases of HIV transmission from mother-to-infant
has plummeted since its peak nearly two decades ago. The watershed was in 1994 when
the results of Pediatric AIDS Clinical Trial Group protocol 076 (PACTG 076) demonstrated
that the perinatal transmission rate could be decreased by nearly 70% by taking
antiretroviral (ARV) drugs during pregnancy.¹

Adoption of ARV therapy as the standard of care for pregnant women with HIV infection
has led to even further reductions in perinatal HIV transmission. Additional research led
to the findings that giving antenatal ARV therapy (initially dual- and then triple-combi-
nation) was associated with a decline in perinatal HIV transmission to less than 2%.²
By 2009 there were less than 200 HIV-infected infants born in the United States, 5 of whom
were born in New Jersey.³

Every diagnosis of an infant who is infected with HIV represents a missed opportunity for
prevention. What are the on-going obstacles to elimination HIV transmission to infants? Contributing factors include rising HIV infection rates in women of childbearing age; absent or delayed prenatal care or lack of
routine prenatal HIV testing; illicit drug use; acute infection in pregnancy; and adherence
issues with prescribed ARV therapy for pregnant women with HIV infection. Women
whose infants become infected with HIV are often women who are vulnerable and hard to
reach with traditional maternal child health and HIV services.

Elimination of perinatal transmission of HIV is dependent on a range of effective services
for pregnant women who test HIV-positive, the prevention of new infections in women
and men of childbearing age and screening of all pregnant women for HIV. CDC has
recommended HIV testing as a part of routine prenatal screening since 2006 and
the American College of Obstetricians and Gynecologists (ACOG) since 2008.⁴ In some
states, including New Jersey, HIV testing in pregnancy is regulated by state law.

Perinatal HIV transmission in New Jersey

With leadership from the New Jersey Department of Health and Senior Services
(NJDHSS), New Jersey continues to work on multiple fronts to reach the goal of
elimination of perinatal transmission. From surveillance to clinical care to
education of healthcare providers and consumers, New Jersey has implemented
a range of strategies to move toward that goal.

As a state with a high proportion of HIV cases among women – 34% of those living with HIV
in New Jersey are women – New Jersey pioneered the first database to monitor perinatal
exposure and transmission rates. New Jersey’s Enhanced Perinatal Surveillance includes a
comprehensive review and abstraction of actual prenatal records, labor and delivery records,
and newborn pediatric records. Together with data from matched HIV/AIDS registry and
birth files, the NJDHSS, Division of HIV, STD, and TB Services (DHSTS) can:
- Gather outcome indicator information to evaluate compliance with prevention guidelines
- Identify missed opportunities for prevention
- Monitor the rate of perinatal transmission in New Jersey

New Jersey’s Enhanced Perinatal Surveillance system indicates that, as of June 30, 2010, there
have been 1,265 confirmed cases of infants perinatally infected with HIV in New Jersey since
1993.⁵ Children exposed to, and infected with, HIV through mother-to-child transmission have
been reported in every county in the state. The rate of transmission to infants born to mothers
living with HIV has dropped from 16% in 1993–1999 to 2% in 2011.⁶ This decrease is due to:
- Earlier diagnosis of HIV infection in pregnant women
- Provision of appropriate obstetrical and pediatric care
- The use of ARV agents during pregnancy, labor and delivery, and treatment of the newborn

PACTG 076 was a randomized, double-blinded, placebo-controlled study that was considered definitive proof of the effectiveness of zidovudine.
The study, which went from April 1991 to December 1993, included 477 HIV-
infected pregnant women (14 to 34 weeks gestation) with CD4 cell counts
above 200 who had not received ARV therapy during the current pregnancy.
The study found the proportions of infants infected at 18 months of age
were 8.3% in the zidovudine group and 25.5 percent in the placebo group.
HIV testing of pregnant women: New Jersey’s 2007 legislation

The implementation of New Jersey’s 2007 legislation (NJ P.L. 2007.c.218) regarding HIV testing in pregnancy has had an impact on both health professionals caring for pregnant women and women in care. The legislation replaced a law from early in the HIV epidemic, which required the routine “offering” of HIV testing to pregnant women. Under the 2007 legislation HIV testing is included in routine prenatal testing using an “opt-out” approach. That is, the HIV test is conducted routinely, along with the standard battery of prenatal blood tests, unless the woman declines. A separate written informed consent is no longer required in New Jersey for HIV testing during pregnancy.

The New Jersey legislation closely follows CDC’s September 2006 Revised Recommendation for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings. In fact, one important aspect of New Jersey’s legislation is that it specifically notes that New Jersey regulations regarding HIV testing in pregnancy should follow CDC recommendations, so that practice can change to comply with CDC recommendations without having to change the legislation itself.

The implementation of New Jersey’s 2007 legislation (NJ P.L. 2007.c.218) regarding HIV testing of pregnant women: In combination with education of health-care providers and technical assistance to hospitals, the 2007 legislation on HIV testing in pregnancy has been implemented across the state without difficulty. The opt-out approach to testing does not make any assumptions about a particular woman’s risk for HIV. It assumes that she has had unprotected sex (in order to get pregnant) and, as such, could be at risk for HIV. In combination with education of health-care providers and technical assistance to hospitals, the 2007 legislation on HIV testing in pregnancy has been implemented across the state without difficulty. The opt-out approach to testing does not make any assumptions about a particular woman’s risk for HIV. It assumes that she has had unprotected sex (in order to get pregnant) and, as such, could be at risk for HIV. In combination with education of health-care providers and technical assistance to hospitals, the 2007 legislation on HIV testing in pregnancy has been implemented across the state without difficulty.

Prior to conducting HIV testing, the healthcare provider must give the patient information about:

- HIV and AIDS and how HIV is spread, including sexually and via mother-to-child transmission during pregnancy, at delivery, and through breastfeeding
- HIV testing, HIV testing process, and the fact that testing is routine for all pregnant women in New Jersey
- The benefits of testing for the mother and her baby
- The available medical treatment for her, if she is HIV-positive
- The interventions available to reduce the infant’s risk of HIV infection

The available medical treatment for her, if she is HIV-positive

The opt-out approach to testing does not make any assumptions about a particular woman’s risk for HIV. It assumes that she has had unprotected sex (in order to get pregnant) and, as such, could be at risk for HIV. In combination with education of health-care providers and technical assistance to hospitals, the 2007 legislation on HIV testing in pregnancy has been implemented across the state without difficulty.

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Examples of written information informing women of HIV testing

“HIV and Other Important Pregnancy Tests” is a small tear-off pad that lists routine prenatal tests including HIV (ACOG, 2007), available in Spanish as well as English. It can be ordered from ACOG (www.acog.org or 800-762-2264). By summer 2012 it can be down-loaded at www.womenandhiv.org (look for the “Purple Folder”).

“One Test, Two Lives” campaign includes patient handouts and materials for clinicians, including a handout that describes how to respond when a client is unsure about HIV testing (CDC, 2008). The “One Test, Two Lives” materials can be downloaded or ordered from http://www.actagainstaids.org/provider/ottl/index.html. These materials are also available at the National Prevention Information Network (NPIN): www.cdcnpin.org.
Surveillance has shown that an increasing proportion of women whose HIV was undiagnosed at delivery had seroconverted during pregnancy. In other words, many pregnant women with undiagnosed HIV actually acquired HIV very recently; possibly after first trimester testing would have been undertaken. Women who acquire HIV while pregnant or breastfeeding are at increased risk of transmitting HIV to their infants (in comparison to women who acquired HIV before they became pregnant). Because of this risk, CDC recommends a second HIV test in the third trimester in geographic areas with elevated HIV incidence (>17 cases per 100,000 person years), which includes New Jersey. The New Jersey legislation reflects this recommendation. While repeat HIV testing has been done for medical indications in New Jersey, routine third trimester testing is a new requirement for obstetric care providers.

Like HIV testing in early pregnancy, third trimester testing requires an opt-out approach. The legislation is silent about the specific timing of third trimester testing but CDC recommends that it be done before 36 weeks. The NJDHSS “best practices” document leaves to clinicians the decision about how best to integrate third trimester testing into routine care. The test may be done early in the third trimester when other routine tests are undertaken or it can be done closer to 34 weeks to lengthen the interval between the first and second HIV tests.

New Jersey delivery hospitals have put procedures in place for assessing the woman’s HIV status at admission to the labor and delivery unit. These procedures include: rapid HIV testing; informing women that HIV is included in the tests ordered in the labor setting; assuring that zidovudine is available in intravenous formulation for women in labor; and maintaining supply of oral zidovudine syrup and other ARVs for newborns. Note that rapid HIV testing is considered the standard of care as per NJDHSS 2001 recommendations as it makes it possible to administer ARVs to the mother during labor and the child immediately after delivery.

Women who have not Routinely accessed prenatal care may not have had an HIV test or have results available in labor. Rapid testing in labor assures that women testing HIV positive in labor and their infants can receive appropriate ARV interventions to decrease the risk of HIV transmission. Anecdotal reports and case reviews indicate that a number of women who are HIV positive are being diagnosed in the peripartum period (personal communication Burr/Ryan).

Some women may enter prenatal care or present in labor knowing that they have HIV infection, but may be reluctant to share that information with providers. Routine testing in the third trimester and in labor affords opportunity to test those who access care sporadically and facilitate access to HIV-related care and treatment if found to be HIV-infected. Clinicians should carefully follow up with any woman who declines testing to learn her reasons and to reassure her that HIV testing is not risk-based and is routine across New Jersey for pregnant women.
NEW JERSEY PROVIDER GUIDE TO RAPID HIV TESTING IN LABOR & DELIVERY
Providing Information to Women in Labor with Unknown HIV Status
Regarding Routine, Rapid HIV-1 Antibody Testing

Eligibility: New Jersey’s P.L. 2007, c. 218 (available at: http://www.njleg.state.nj.us/2006/Bills/PL07/218.HTM) requires that all pregnant women routinely have an HIV test early in prenatal care and re-tested during the third trimester. If a pregnant woman’s HIV status is unknown or if she was not re-tested during the third trimester, she should be tested (or re-tested) during labor. A woman may decline testing; however, her newborn will be tested if the mother’s HIV status is unknown unless the parents refuse infant testing on religious grounds (“in conflict with their religious tenets and practices”). In such circumstances, the parents must provide a written statement of their objection. The following is a guide to help you inform women in labor about routine rapid HIV testing and its importance in preventing perinatal HIV transmission, as required by law. Background information/instructions are written in regular type; scripted words that you can use, are shown in italics.

Script:
The following is a guide to help you inform women in labor about routine rapid HIV testing and its importance in preventing perinatal HIV transmission, as required by law. Background information/instructions are written in regular type; scripted words that you can use, are shown in italics.

Introduction to HIV testing in labor & delivery:
• HIV rapid testing is routine in New Jersey for all women in labor who have not had an HIV test in the third trimester.
• We don’t have any record of your HIV test results in the last three months.
• We routinely do a rapid HIV test during labor because so much can be done to protect the baby if the mom has HIV. We also do it to help women live a healthier, longer life.

I have three things I am going to talk to you about:
• A special HIV test that is required by law in New Jersey.
• Why this test is important for you and your baby.
• What happens when the test result comes back.

A special HIV test is required by law in New Jersey
• It is important for you and your baby that you have a “rapid” HIV test. HIV is the virus that causes AIDS.
• This test can give us results quickly.
• If you decline to have the test, the law requires that we test your baby after birth.

Why this test is important
• Human immunodeficiency virus (HIV) is the virus that causes AIDS.
• HIV is a serious illness that can affect a woman’s health and her baby’s health.
• One of the ways HIV is spread is by unprotected sex. Therefore, all pregnant women may be at risk for HIV infection.
• HIV can be passed from a mother to her baby during pregnancy, at delivery, and through breastfeeding.
• If you have HIV infection, rapid testing will allow us to find out within the next hour so that we can give you medication during labor to reduce the risk of passing HIV to your baby.
• Your baby will receive the same medication after birth.
• Without treatment, the chance the baby will be infected is about 25%, or 1 in 4.
• We know if women are given medication during labor and delivery and their babies get the medication right after birth, we can reduce the risk of HIV transmission to about 5%, or 1 in 20 babies.

What happens when the test result comes back?
• You will receive a preliminary result about an hour after your blood is drawn.
• If the rapid HIV test is negative, no further testing is needed at this time. It is most likely that you do not have HIV. However, the test may not show a very recent infection.
• If the rapid test is negative, it is OK to breast feed your baby.

If the rapid HIV test is positive
You probably have HIV infection and your baby may have been exposed to HIV.
• The test is a screening test that provides a preliminary result, and a false-positive result can happen.
• We always do a second test to confirm rapid tests that are positive.
• To be safe, it is best to start medicine to help prevent transmission of HIV to your baby, while we wait for the confirmatory test result.
• Experts recommend zidovudine through your IV fluids into your vein to reduce the chance your baby will get HIV.

Medical treatment
Your doctor will decide which medicines will be best for you and your baby and will discuss them with you before starting them.
After your baby is born, he/she will start taking zidovudine syrup.
• These medicines have been studied in pregnant women and newborns and there have been no serious side effects.
• You should wait until we have the results of the confirmatory test before you start breastfeeding.

If the confirmatory test is negative
• You and your baby will immediately be taken off any medication that was started.

If the test is confirmed as positive
• All medication that was started to help prevent HIV transmission will continue.
• If treatment is started, a doctor or nurse will discuss again any consequences of taking the medication.
• Your baby will need more testing for HIV infection.
You will be referred to a physician for your own medical care – there are medications to help keep you healthier longer. You will also be referred to a healthcare provider who will take care of your baby’s medical needs.

HIV test results are confidential. There are laws to protect people with HIV from discrimination.
Newborn Testing

Under the new legislation, newborn HIV testing is required in certain situations:

- When the mother’s HIV status is still unknown or undocumented when the infant is born
- When the mother was not tested for HIV during the third trimester (or during labor, as labor is considered part of the third trimester), even if she was tested in the first trimester

Because maternal antibodies remain detectable by HIV antibody testing through the first 6 to 18 months of life, newborn HIV antibody testing reveals the mother’s HIV status, not necessarily the infant’s. Newborn HIV antibody testing should be done as soon as possible after birth so that infant prophylaxis with oral zidovudine can be initiated within the first 6–12 hours of life as recommended in the Perinatal Guidelines (see next section).

Birthting facilities should assure that the mother’s HIV status is documented in the record sent to the newborn nursery and that routine HIV testing is included as a standing admission order for any newborn whose mother’s HIV status is unknown. Oral zidovudine syrup must be available in the hospital/birthting facility for the infant’s initial prophylaxis doses. A prescription must be provided for the remaining doses. (See “Management of HIV-exposed newborns” later in this article.)

Parents may refuse testing for religious reasons if they provide a written statement of their objection. This statement must remain in the newborn’s medical record.

Follow-up for HIV-exposed newborns

The legislation also requires that NJDHS establish a comprehensive follow-up testing program for HIV-exposed newborns who test HIV positive or whose mothers test positive. These services are already in place across the state through the New Jersey Family-Centered HIV Care Network. The network has seven sites across the state that receive funding from NJDHS through a federal grant from Part D of the Ryan White CARE Act (http://www.nj.gov/health/fhs/hivcare/regional.shtml). The pediatric HIV specialists and multi-disciplinary care teams at these programs have provided expert HIV care to children and families across New Jersey for nearly twenty years and are well-positioned to provide diagnostic testing and ongoing care for newly identified HIV-exposed infants and their families. HIV-exposed infants will need HIV diagnostic testing starting by 2 to 4 weeks of age and continued follow-up until 18 months of age if found to be uninfected.

The diagnosis and management of HIV-exposed and HIV-infected infants is discussed in detail in another U.S. Department of Health and Human Services document Antiretroviral Management of Infants and Children with HIV-1 Infection, a “living document” updated regularly by the Pediatric ARV Working Group at the AIDSInfo site (www.aidsinfo.nih.gov).

Perinatal HIV/AIDS reporting requirements in New Jersey

Beginning in 1992 all cases of children born to mothers who are HIV positive must be reported to the NJDHS. Any medical practitioner delivering or providing care to a child known to be perinatally exposed to HIV, or ordering a test resulting in the diagnosis of perinatally exposed HIV, is required to report in writing such condition to the NJDHS, DHSTS within 24 hours. Reports must be made on forms supplied by the NJDHS, DHSTS. For assistance with the reporting of perinatal exposures, or to request reporting forms, call (609) 984-5940.

Conclusion

New Jersey’s legislation is helping to assure that pregnant women routinely receive HIV testing and, if HIV-infected, have the opportunity to benefit from ARV medications and other interventions to support their health and to decrease the risk of HIV transmission to their infants. In addition, pregnant women living with HIV need access to the most up-to-date guidance on management of HIV in pregnancy. The Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission’s (the “Panel”) Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States (the “Perinatal Guidelines”), 2011 discusses in detail the management of pregnant women with HIV infection. The Perinatal Guidelines are a “living document” available online through the U.S. government site, AIDS Info (www.aidsinfo.nih.gov) and are updated regularly by the Panel. For the most current recommendations, check the online version. Key recommendations from the Perinatal Guidelines are outlined in the second half of this article.
Reducing the Risk of Perinatal HIV Transmission in New Jersey and the U.S.: Legal and Clinical Strategies

Care of pregnant HIV-positive women

The Perinatal Guidelines are updated at least annually and were most recently released on September 14, 2011. The Panel reaffirmed many of the current recommendations but added some new ones and updated the literature on others. Unless otherwise cited, information in the sections below is from the 2011 Perinatal Guidelines.

How ARV therapy reduces perinatal HIV transmission

The Panel continued its longstanding recommendation for the three components of ARV prophylaxis. Perinatal transmission of HIV is most effectively prevented when ARVs are given during the antepartum, intrapartum, and neonatal periods. These interventions reduce maternal viral load and provide infant pre- and post-exposure prophylaxis:

- **Pre-exposure prophylaxis (antenatal and intrapartum periods):** Antenatal ARV administration reduces maternal viral load in both blood and genital secretions, which is particularly important if the mother’s pre-pregnancy viral load was high. In fact, even in women with viral loads of < 1,000 copies/mL, ARVs have still been shown to reduce the transmission of HIV to the infant. The mechanism by which the drugs protect the infant is of particular importance during passage through the birth canal. This is the time when the infant is maximally exposed to virus. Thus, giving the infant pre-exposure prophylaxis by administering ARVs that cross the placenta and achieving adequate drug levels is key.

- **Infant post-exposure prophylaxis (neonatal period):** Provides protection from virus that may have passed through the fetal/infant circulation, through maternal-fetal circulation (via the umbilical cord) during maternal contractions, or by the infant swallowing the virus during passage through the birth canal.

Research from clinical trials

The 2011 Perinatal Guidelines update includes an extensive review of the existing and newly reported clinical trial results that informed the Panel’s recommendations. Combination therapies have been found in clinical trials to be more effective, in general, than single-drug regimens in reducing perinatal HIV transmission.

A number of short-course ARV regimens, such as those with zidovudine; zidovudine plus lamivudine; single-dose nevirapine; and single-dose nevirapine combined with either short-course zidovudine or zidovudine/lamivudine, have all demonstrated efficacy in trials in resource-limited settings. Even in patients with advanced disease, the use of ARV drugs is extremely effective in reducing perinatal transmission. Giving ARVs antepartum, intrapartum, and neonatal is more effective than any lesser combination.

Clinical trials have shown that longer duration antenatal ARV prophylaxis (initiating at 28 weeks gestation) more effectively prevents transmission than shorter duration ARV prophylaxis (initiation at 36 weeks gestation), which suggests that a significant proportion of maternal to fetal transmission occurs during 28 and 36 weeks. Because each additional week that the mother takes triple-drug therapy amounts to a 10% reduction in the risk of transmission (after adjusting for viral load, mode of delivery, and sex of the infant), the Perinatal Guidelines recommend:

- **Women who require ARV therapy for their own health:** ARV drugs should be started as soon as possible.

- **Women who do not require immediate initiation of therapy for their own health:** ARV drugs should be initiated without delay after the first trimester (see Table 1, which appears later in this article, for a summary of preferred and alternative regimens for HIV-infected pregnant women).

In certain situations, it is only possible to administer infant prophylaxis, as maternal antepartum and intrapartum therapy is not an option if the mother has received no prenatal care and delivery occurs quickly. The standard infant ARV prophylaxis of 6 weeks of zidovudine reduces HIV transmission more effectively when compared to no prophylaxis if the mother has not had antenatal prophylaxis.

The Perinatal Guidelines cite a recent study presented at the 2011 Conference on Retroviruses and Opportunistic infections that addressed the question of the optimal prophylaxis for infants whose mothers had not received ARV prophylaxis. It compared the standard six weeks of zidovudine with two other regimens. It demonstrated that combination regimens reduced the risk of intrapartum HIV transmission by nearly 50% as compared with infant prophylaxis with zidovudine alone (Nielsen-Saines K, Watts DH, Santos VV, et al. 2011). Based on these findings, combination ARV prophylaxis is now the recommendation in United States for infants whose mothers did not receive antenatal regimens.
All pregnant women who require therapy for their own health should receive a combination antepartum ARV drug regimen containing at least three drugs for treatment, which will also reduce the risk of perinatal transmission.

Combination antepartum drug regimens are also recommended for prevention of perinatal transmission in women who do not yet require therapy for their own health.

ARV prophylaxis is more effective when given for a longer than a shorter duration. Therefore, ARV drugs should be started as soon as possible in women who require treatment for their own health, and without delay after the first trimester in women who do not require immediate initiation of therapy for their own health, although earlier initiation can be considered in these women as well.

In the absence of antepartum administration of ARV drugs, ARV drugs should be administered intrapartum in combination with infant ARV prophylaxis to reduce the risk of perinatal transmission; if antepartum and intrapartum ARV drugs are not received, infant ARV prophylaxis should be provided.

Adding single-dose intrapartum/newborn nevirapine to the standard antepartum combination ARV regimens used for prophylaxis or treatment in pregnant women in the United States is not recommended. This is because the drug does not appear to provide additional efficacy in reducing transmission and it may be associated with development of nevirapine resistance.

Breastfeeding is not recommended for HIV-infected women in the United States — including those receiving combination ARV therapy — because safe, affordable, and feasible alternatives are available.

Maternal HIV viral load and perinatal transmission

Mother-to-child transmission can occur even when viral loads are very low or undetectable. PACTG 076 found no identifiable maternal HIV viral load threshold below which there was no risk of transmission to the infant. Zidovudine, however, was found to reduce HIV transmission to the newborn regardless of maternal HIV copy number. Therefore the Perinatal Guidelines continue to recommend that all HIV-infected women be counseled and administered ARVs during pregnancy.

Pre-conception counseling and care

Preconception care, including comprehensive family planning, is now recommended for all women of reproductive age by a number of national organizations including CDC and ACOG. The Perinatal Guidelines also emphasize the importance of preconception care for women living with HIV. With the goal of optimizing maternal and fetal outcomes if pregnancy is desired and identifying potential risk factors for adverse events, preconception care should be an ongoing discussion that is tied into the patient’s routine primary care and addresses the needs of women as they journey through different stages of reproductive life.

Since women may be reluctant to bring up the topic, healthcare providers should initiate and document a nonjudgmental conversation with their clients living with HIV about their childbearing plans.

This ongoing conversation should be an integral part of women’s routine HIV care during which the healthcare provider should:

- Discuss the patient’s reproductive options, assess pregnancy intentions, and when necessary, make referrals to experts in HIV and women’s health.
- Offer women effective and appropriate contraception, considering the potential interactions between ARVs and certain contraceptives whose efficacy can be lowered by interactions with the ARV therapy.
- Counsel on safe sexual practices that prevent HIV transmission to sexual partners, prevent acquisition of other STIs, and reduce the risk of infection with more virulent strains of HIV.
- Counsel on avoidance of alcohol, tobacco, and drugs.

(Continued on next page)
Pre-conception counseling and care (cont’d)

- Educate and counsel women about risk factors for perinatal transmission of HIV, strategies to reduce transmission, the potential effects of HIV and its treatment on pregnancy, and the recommendation that HIV-infected women in the United States not breastfeed.
- Use the preconception period in women who are contemplating pregnancy to adjust ARV regimens to exclude efavirenz or other drugs with teratogenic potential.
- For women who are on ARV therapy for their own health and who want to get pregnant, make a primary treatment goal the attainment of a stable, maximally suppressed maternal viral load.
- Evaluate and appropriately manage therapy-associated side effects such as hyperglycemia, anemia, and hepatotoxicity.
- Evaluate the need for appropriate prophylaxis or treatment for opportunistic infections (OIs).
- Administer medical immunizations (e.g., influenza, pneumococcal, or hepatitis A and B vaccines) as indicated.
- Encourage sexual partners to receive HIV testing and, if infected, counseling and appropriate HIV care.

For additional information about preconception care, refer to the report from CDC’s Preconception Work Group.  

HIV-concordant and discordant couples

The September 2011 Perinatal Guidelines include a specific section on reproductive options both for serodiscordant couples and couples where both are HIV-infected. While observational studies have shown a decreased rate of transmission of HIV among HIV-discordant couples when the infected partner is on ARV therapy, the updated Perinatal Guidelines review the findings of HIV Prevention Trials Network (HPTN) 052, a recent randomized clinical trial that showed a dramatic decrease in HIV transmission to uninfected partners. HPTN 052 evaluated whether immediate versus delayed treatment of the infected partner with a CD4 count of 350–550 cells/mm³ could prevent transmission to the uninfected partner. Early treatment reduced the risk of infection by 96% – the first data from a randomized trial to show that treatment could reduce the risk to an uninfected partner. However, it is important to note that no single method, including ARV therapy, is fully protective against transmission.

While observational studies have shown a decreased rate of transmission of HIV among HIV-discordant couples when the infected partner is on ARV therapy, it is important to note that no single method, including ARV therapy, is fully protective against transmission.

Panel’s Recommendations  HIV-concordant and discordant couples

In a serodiscordant couple who wishes to conceive, initiation of ARV therapy for the HIV-infected partner is recommended if the infected partner has a CD4 count <550 cells/mm³. For HIV-infected individuals with CD4 counts >550 cells/mm³, initiation of ARV therapy could be considered. If therapy is initiated, maximal viral suppression is recommended before conception is attempted.

In addition to recommendations around initiation of ARV therapy in discordant couples, the Perinatal Guidelines also recommend specific interventions for couples considering conception:
- Partners should be screened and treated for genital tract infections before attempting to conceive.
- For an HIV-infected female with an HIV-uninfected male partner, the safest conception option is artificial insemination, including the option of self-insemination with her partner’s sperm during the peri-ovulatory period.
- For HIV-infected men with an HIV-uninfected female partner, the use of sperm preparation techniques coupled with either intrauterine insemination, in vitro fertilization, or intracytoplasmic sperm injection should be considered if using donor sperm from an HIV-uninfected male for insemination is unacceptable.
- Data are insufficient at the current time to recommend peri-conception administration of ARV pre-exposure prophylaxis for HIV-uninfected partners to reduce the risk of sexual transmission.
The Perinatal Guidelines note that the initial evaluation of an HIV-infected pregnant woman should include the standard antenatal assessment, as well as the following:

- Review of prior/past:
  - HIV-related illnesses
  - CD4 cell counts
  - Plasma HIV viral load
- Assessment of current:
  - CD4 cell count
  - Plasma HIV viral load
- Assessment of the need for prophylaxis against opportunistic infections (OIs)
- Evaluation of immunization status
- Baseline complete blood cell count (CBC), renal, and liver function testing
- HLA-B*5701 testing, if abacavir use is anticipated
- History of prior and current ARV drug use, including prior ARV use for prevention of perinatal transmission of HIV or for treatment of HIV disease, and history of adherence problems
- Results of prior and current HIV ARV drug-resistance studies
- Assessment of supportive care needs.

Discussions with women about the initiation of ARV therapy during pregnancy should include the following considerations:

1. Maternal risk of disease progression and benefits and risks of initiation of therapy for maternal health
2. Benefit of combination ARV regimens for preventing perinatal transmission of HIV
3. Potential adverse effects of ARV drugs for mothers, fetuses, and infants, including potential interactions with other medications
4. Limited long-term outcome data for women who temporarily use ARV drugs during pregnancy (for prophylaxis) and infants who are exposed to ARVs in utero
5. The possibility of developing ARV resistance, focusing on the need for strict adherence

The choice of which ARV to use should be based on the same principles that are followed when choosing regimens for non-pregnant females, unless there are compelling maternal or fetal safety issues. A regimen should be durable (less likely to cause resistance), tolerable, and simple enough for pregnant women so that there are future options, either if they are stopping medications after delivery, or if they must continue the regimen based on adult guidelines to treat HIV.

The following factors should be considered when individualizing ARV therapy regimens:
- Comorbidities
- Patient adherence potential
- Convenience
- Potential adverse maternal drug effects
- Potential drug interactions with other medications
- Results of genotypic resistance testing
- Pharmacokinetic (pk) changes in pregnancy
- Potential teratogenic effects and other adverse effects on fetuses or newborns

The Perinatal Guidelines emphasize that when selecting a regimen for a pregnant woman, it should include at least one NRTI that has a high potential for placental transfer in the dual NRTI backbone. The Perinatal Guidelines include a detailed table (Table 5 in the Guidelines document) that reviews each ARV drug, its available formulation, dosing recommendations, recommendations for use in pregnancy, pharmacokinetics in pregnancy and any other concerns about use in pregnancy.

The 2011 Perinatal Guidelines reaffirm the importance of ARV therapy for women who are currently on ARV treatment.
Reducing the Risk of Perinatal HIV Transmission in New Jersey and the U.S.: Legal and Clinical Strategies

The Perinatal Guidelines include detailed recommendations for initiating ARVs in those for whom the question of when to start ARV prophylaxis is complex: antiretroviral naïve women who have never received ARV therapy and for whom treatment is not recommended or is optional for their own health. The fetus is most susceptible to teratogenic effects of drugs in the first trimester of pregnancy so a woman who does not need ARV therapy for her own health may consider delaying treatment until after 12 weeks gestation. The discussion with her should include a review of her own health status and the benefits and risks of delaying treatment. While most perinatal transmission occurs late in pregnancy or during labor and delivery, a smaller proportion occurs early in utero. The 2011 Perinatal Guidelines review of a French study that suggested that early and sustained control of viral load at a low level can further decrease transmission – led to the Panel's note that “earlier initiation of therapy may be more effective in reducing in utero transmission”.

The Perinatal Guidelines reaffirm the importance of ARV therapy for women who are currently on ARV treatment, and women who had previously received ARV treatment or prophylaxis but are not currently receiving it. The Panel notes the importance of ARV resistance testing when selecting ARVs for these groups of women.

Women with HIV viral loads above the threshold for resistance testing (e.g., >500–1,000 copies/mL), should conduct ARV resistance testing before starting ARV therapy. However, when HIV is diagnosed late in pregnancy (i.e., third trimester), ARV drugs should be initiated while waiting for results of resistance testing.

Perinatal Guidelines vs Adult/Adolescent Guidelines

The September 2011 Perinatal Guidelines predate the current version of Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents (http://aidsinfo.nih.gov) by about 6 months. The March 27, 2012 version of the Adult and Adolescent Guidelines err in favor of starting persons with HIV on ARV therapy earlier, even if they have CD4 cell counts above 500. The Adult and Adolescent Guidelines recognize that “a secondary goal of ARV therapy is to reduce an HIV-infected individual’s risk of transmitting the virus to others. Although … this public health benefit … is significant, Panel recommendations on when to initiate ART are based primarily on the benefit of treatment to the HIV-infected individual.” Always check the current version of the guidelines for the most recent recommendations.

Table 1. Preferred and alternative regimens for HIV-infected pregnant women

<table>
<thead>
<tr>
<th>HIV-infected pregnant women who are ARV-naive</th>
<th>2 NRTIs</th>
<th>+PI</th>
<th>OR an NNRTI</th>
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<tbody>
<tr>
<td><strong>Preferred Regimen</strong></td>
<td></td>
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</tr>
<tr>
<td>Zidovudine/lamivudine</td>
<td>Lopinavir/ritonavir OR Atazanavir/ritonavir</td>
<td>Nevirapine if CD4 cell counts &lt;250 cells/mm³</td>
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</tr>
<tr>
<td>Tenofovir/lamivudine or emtricitabine OR Abacavir/lamivudine</td>
<td></td>
<td>Do not initiate nevirapine in treatment-naive women with CD4 cell counts &gt;250 or if transaminase levels are elevated.</td>
<td></td>
</tr>
</tbody>
</table>

**HIV-infected pregnant women who are currently receiving ARV therapy:** In general, pregnant women receiving and tolerating an ARV therapy regimen that is currently effective in suppressing viral replication should continue on the regimen.

**Note:** Efavirenz, the preferred NNRTI for nonpregnant adults, is not recommended for use in the first trimester of pregnancy, and alternative ARV regimens that do not include efavirenz should be considered in women who are planning to become pregnant. Use of efavirenz can be considered after the first trimester, based on clinical indication.

In reviewing the above table, keep in mind that the Perinatal Guidelines focus on individual drugs rather than trying to present regimens, as considerations are drug-specific not regimen-specific.
Antepartum care (cont’d)

When ARVs have been used only for prevention of perinatal transmission, the short-term and long-term impact on the mother’s health of discontinuation post-partum is unknown at this point. An ongoing study is looking at the risks versus benefits of stopping ARVs post-pregnancy in women whose CD4 count is high (i.e., usually defined as above 500 or 550/mm³, see adult and adolescent treatment guidelines at http://www.aidsinfo.nih.gov/guidelines for additional information). Regardless, the decision to continue or discontinue ARVs should be made in consultation with the woman. If and when drugs are stopped postpartum, the Perinatal Guidelines recommend that all ARV drugs be stopped simultaneously. When a woman is on an NNRTI-based regimen, the dual-NRTI backbone should be continued for some time after stopping the NNRTI to reduce the development of NNRTI resistance. An alternative to this would be to replace the NNRTI with a protease inhibitor (PI), while continuing the NRTI backbone.

Acute HIV Infection

The 2011 Perinatal Guidelines now include a new section on the management of acute HIV infection in pregnancy or breastfeeding. Acute HIV infection is associated with an increased risk of perinatal HIV infection and may account for a significant proportion of the perinatal transmission still occurring in the United States. Studies estimate that 40–90% of patients with acute infection experience symptoms of acute retroviral syndrome which can include fever, arthralgia, skin rash, lymphadenopathy, pharyngitis, and other symptoms. Because these symptoms are similar to those of a number of common conditions (“flu-like illnesses”), healthcare providers may not recognize these as related to HIV infection.

Providers caring for pregnant or breastfeeding women should have a high index of suspicion for HIV if a patient presents with these flu-like symptoms. She may not report high risk behaviors but may be unaware of those behaviors of her sexual partner. Because antibody to HIV may not yet be detectable, a plasma HIV RNA test should be done in conjunction with an HIV antibody test to diagnose acute HIV infection. The Perinatal Guidelines recommend repeat HIV antibody testing in the third trimester for women with high-risk behaviors or living in high prevalence jurisdictions (which, by definition, includes New Jersey). If the HIV RNA test or the antibody test is positive, the pregnant women with acute or recent HIV infection should start a combination ARV drug regimen as soon as possible to prevent mother-to-child transmission, with the goal of suppressing plasma HIV RNA to below detectable levels. HIV genotypic resistance testing should also be done initially and the regimen adjusted, if necessary, to optimize virologic response. Treatment should be started while awaiting the results of the resistance testing. Because clinically significant resistance is less common in protease inhibitors (PI) than in NNRTIs, the Perinatal Guidelines recommend starting with a PI-based regimen with the choice of drugs based on the Panel’s recommendations.

Pregnant and breastfeeding women should be counseled on safer sexual practices and other strategies to prevent HIV transmission. Evidence suggests that pregnancy may be a time when risk of acquiring HIV is higher.

Evidence suggests that pregnancy may be a time when risk of acquiring HIV is higher.
Intrapartum care: ARVs

The majority of the Panel’s recommendations for care of women with HIV infection during labor and delivery were reaffirmed in the 2011 update. Intravenous zidovudine continues to be recommended for all pregnant women with HIV, unless they have hypersensitivity, even those with known or suspected zidovudine resistance. Zidovudine’s use in the intrapartum period is based on its unique characteristics and its proven track record.

Intrapartum intravenous zidovudine is recommended for all HIV-infected pregnant women, regardless of their antepartum regimen, to reduce perinatal transmission of HIV.

For women who are receiving a stavudine-containing antepartum regimen, stavudine should be discontinued during labor while intravenous zidovudine is being administered.

Women who are receiving an antepartum combination ARV drug regimen should continue this regimen on schedule as much as possible during labor and before scheduled cesarean delivery.

Women receiving fixed-dose combination regimens that include zidovudine should receive intravenous zidovudine during labor while other oral ARV components are continued.

Women of unknown HIV status who present in labor should undergo rapid HIV antibody testing. If the results are positive, a confirmatory HIV test should be done as soon as possible and maternal/infant ARV drugs should be initiated pending results of the confirmatory test. If the confirmatory HIV test is positive, infant ARV drugs should be continued for 6 weeks; if the test is negative, the infant ARV drugs should be stopped.

Intravenous zidovudine is recommended for HIV-infected women in labor who have not received antepartum ARV drugs and infant combination ARV prophylaxis is recommended for 6 weeks (see Infant ARV Prophylaxis).

Panel’s Recommendations

It is not clear whether cesarean delivery after rupture of membranes or onset of labor provides benefit in preventing perinatal transmission. Management of women originally scheduled for cesarean delivery who present with ruptured membranes or in labor must be individualized.

Intrapartum care: cesarean section

The Panel continues to recommend cesarean section for women with HIV with an HIV RNA level >1000 copies/ml. Scheduled cesarean delivery is not routinely recommended for pregnant women (on ARV therapy) with plasma HIV RNA levels <1,000 copies/mL near the time of delivery. It is unclear from the data that a cesarean further reduces the already low rate of transmission. This decision should be individualized based on discussion between the obstetrician and the mother.

The Panel noted the importance of accurately determining the gestational age by last menstrual period and ultrasound, when cesarean is being planned.

Panel’s Recommendations

Scheduled cesarean delivery at 38 weeks’ gestation is recommended for women with HIV RNA levels >1,000 copies/mL near the time of delivery, irrespective of administration of antepartum ARV drugs, and for women with unknown HIV RNA levels near the time of delivery.

It is not clear whether cesarean delivery after rupture of membranes or onset of labor provides benefit in preventing perinatal 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 RNA level, current ARV regimen, and other clinical factors.

Women should be informed of the risks associated with cesarean delivery; the risks to the woman should be balanced with potential benefits expected for the neonate.
Management of HIV-exposed newborns

The 2011 Perinatal Guidelines include two important changes for the management of newborns exposed to HIV. The Perinatal Guidelines recommend that all HIV-exposed neonates are provided with 6 weeks of a zidovudine chemoprophylaxis regimen. Zidovudine should be initiated as close to the time of birth as possible, preferably within 6–12 hours of delivery. The dose of zidovudine for full-term infants is 4 mg/kg of body weight given twice daily for six weeks. The dosing for premature infants is discussed in detail in the Perinatal Guidelines, which includes a table outlining dosage by gestational age.

Although infants were given zidovudine every 6 hours in PACTG 076, numerous international clinical trials support twice daily dosing for prophylaxis. The Perinatal Guidelines discuss the findings from a clinical trial recently released that compared zidovudine alone to two different combination regimens for infants whose mothers had not received ARV therapy during pregnancy. The risk of perinatal transmission was significantly lower in the two and three-drug regimens compared to zidovudine alone. However, neutropenia was more common in the three-drug regimen. The Perinatal Guidelines present both the three-drug regimen (zidovudine/lamivudine/nelfinavir) and the two-drug regimen (zidovudine/nevirapine) but note that the two drug regimen is less toxic.

Panel’s Recommendations  Management of HIV-exposed newborns

- In the United States, the use of ARV drugs other than zidovudine cannot be recommended in premature infants because of lack of dosing and safety data.
- The use of intrapartum/neonatal zidovudine is recommended regardless of maternal history of zidovudine resistance.
- Infants born to HIV-infected women who have not received antepartum ARV drugs should receive prophylaxis with a combination ARV drug regimen, begun as soon after birth as possible. A randomized, controlled trial has shown that a 2 drug regimen of zidovudine given for 6 weeks combined with three doses of nevirapine in the first week of life (at birth, 48 hours later, and 96 hours after the second dose) is as effective as but less toxic than a 3 drug regimen of zidovudine, nelfinavir and lamivudine. The 2-drug regimen is preferred due to lower toxicity and because nelfinavir powder is no longer available in the United States.
- In other scenarios, the decision to combine other drugs with the 6-week zidovudine regimen should be made in consultation with a pediatric HIV specialist, preferably before delivery, and should be accompanied by counseling of the mother on the potential risks and benefits of this approach.
Conclusion

Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States provides evidence-based guidance for the management of pregnant women with HIV infection, those considering pregnancy, and their newborns. The Panel makes every effort to stay current with the literature and emerging clinical trial results. For clinicians in practice, the Perinatal Guidelines provide an easily accessible source (www.aidsinfo.nih.gov) for the most current recommendations for care. The Perinatal Guidelines cover the spectrum of reproductive health issues for women with HIV and offer an important milestone on the road to elimination of perinatal HIV transmission in the United States.

REFERENCES


9. Table 1 is based on personal communication with Dr. Lynne Mofenson. This table does not appear in the 2011 Perinatal Guidelines and is based on the version of the Guidelines due to be released in summer 2012. Always check the current version of the guidelines before prescribing.
Questions refer to the content of the article and the notes that follow. To receive CME/CE/CEU credit: complete exam, registration, and evaluation forms on-line at www.umdnj.edu/ccoe/aids or fill in the forms on the following pages, and mail or fax to UMDNJ-CCOE (see Registration Form).

1. Which of the following is true about infant testing as per New Jersey’s law on HIV testing in pregnancy:
   A. Testing of newborns is conducted using an “opt-out” approach.
   B. Testing of newborns is conducted using an “opt-out” approach if the mother’s (third trimester) HIV status is not documented.
   C. Testing of all HIV-exposed newborns is mandatory, regardless of the mother’s HIV testing status.
   D. Testing of all HIV-exposed newborns is mandatory if the mother’s (third trimester) HIV status is not documented, unless the mother refuses in writing on religious grounds.

2. The New Jersey law on HIV testing in pregnancy requires which of the following:
   A. Education of the pregnant woman about the HIV test.
   B. An opportunity for the woman to ask questions.
   C. The option for the woman to decline an HIV test.
   D. All of the above.

3. In which of the following ways does zidovudine reduce perinatal transmission of HIV:
   A. By reducing maternal viral load in oral secretions.
   B. By providing maternal pre- and post-exposure prophylaxis.
   C. By increasing maternal viral loads in blood and genital secretions.
   D. By providing protection for the infant from HIV through swallowing the virus during passage through the birth canal.

4. For pregnant women with HIV infection who received antepartum ARVs, delivery by Cesarean section is recommended:
   A. For women whose viral load is >1000 copies late in pregnancy.
   B. At 37 weeks gestation.
   C. If resistant virus is found on genotype testing.
   D. For women whose viral load is undetectable.

5. When prescribing ARVs for pregnant women with HIV, it is important to remember:
   A. The risk of perinatal transmission decreases 10% with each additional week of 3-drug treatment.
   B. Pregnant women are unlikely to adhere to a multi-drug regimen.
   C. Short courses of ARV therapy prevent transmission as effectively as long courses.
   D. ARVs should be discontinued in the first trimester of pregnancy.

6. Women who require ARV therapy for their own health:
   A. Should be started on ARV therapy as soon as possible.
   B. Should be initiated on ARV therapy without delay after the first trimester.
   C. Should be initiated on zidovudine until results of genotypic resistance testing are available and then switched to a more appropriate regimen.
   D. Should be initiated on ARV therapy at 24 weeks gestation.
Questions refer to the content of the article and the notes that follow. To receive CME/CE/CEU credit: complete exam, registration, and evaluation forms on-line at www.umdnj.edu/ccoe/aids or fill in the forms on the following pages, and mail or fax to UMDNJ-CCOE (see Registration Form).

7. Preconception care of the woman living with HIV should include all of the following EXCEPT:
   A. Regular discussions about pregnancy intentions.
   B. Counseling to avoid alcohol, tobacco and drugs.
   C. Administer immunizations (e.g., influenza, pneumococcal, or hepatitis A and B vaccines) as indicated.
   D. Counseling to postpone pregnancy indefinitely.

8. The Perinatal Guidelines recommendations for HIV serodiscordant couples who wish to conceive was influenced by a recently released study which found that:
   A. Sperm washing and in vitro fertilization have become increasingly affordable.
   B. ARV therapy of the HIV-infected partner lowered the risk of transmission to the uninfected partner.
   C. Pre-exposure prophylaxis of the uninfected partner prevented transmissions.
   D. Treatment of genital tract infections had little impact on transmission.

9. All of the following should be done when acute HIV infection is suspected in a pregnant woman EXCEPT:
   A. Conduct an HIV antibody test.
   B. Counsel regarding avoiding breastfeeding until diagnosis is known.
   C. Take a detailed sexual history to rule out HIV exposure.
   D. Conduct a plasma HIV RNA test.

10. The antiretroviral prophylaxis for an infant born to a mother with HIV infection who has not received ARV therapy during pregnancy should include:
    A. Oral zidovudine begun as soon as possible after birth.
    B. Nevirapine orally at birth, 48 hours of age and 96 hours after second dose.
    C. Oral zidovudine twice daily for six weeks.
    D. All of the above.
Reducing the Risk of Perinatal HIV Transmission in New Jersey and the U.S.: Legal and Clinical Strategies

REGISTRATION FORM

In order to obtain continuing education credit, participants are required to:

(1) Read the learning objectives, and review the activity, and complete the post-test.

(2) Complete this registration form and the activity evaluation form on the next page, and record your test answers below.

(3) Send the registration and evaluation forms to: UMDN-J Center for Continuing and Outreach Education
   • VIA MAIL: PO Box 1709, Newark, NJ 07101-1709   • VIA FAX: (973) 972-7128

(4) Retain a copy of your test answers. Your answer sheet will be graded and if you achieve a passing score of 70% or more, a credit letter and the test answer key will be mailed to you within four (4) weeks. Individuals who fail to attain a passing score will be notified and offered the opportunity to complete the activity again.

Online option: This activity will be posted at www.umdnj.edu/ccoe/aids where you may obtain a credit letter upon successful completion of the online post-test and evaluation.

Please note: CE credit letters and long-term credit retention information will only be issued upon receipt of completed evaluation form.

SELF-ASSESSMENT TEST
Circle the best answer for each question.

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– PLEASE PRINT –

First Name  M.I.  Last Name  Degree
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Indicate the type of continuing education credit you wish to obtain as a result of your participation in this activity.

☐ Nurses: 1.35 CNE Contact Hour(s). Contact Hours Claimed: ______

☐ Physicians: 2 AMA PRA Category 1 Credit(s)™: Credits Claimed: ______

☐ General: Continuing Education Units (CEUs) (up to 0.2) Claimed: ______

One credit/contact hour for each hour of participation. Continuing Education Units: one unit per ten hours of participation.
I attest that I have completed this activity as designed. I will report the number of credits/contact hours claimed during my filing of continuing education credit with professional organizations, licensing boards, or other agencies.

Signature  Date

Release date: June 1, 2012 • Expiration date: Credit for this activity will be provided through May 31, 2014.
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The planning and execution of useful and educationally sound continuing education activities are guided in large part by input from participants. To assist us in evaluating the effectiveness of this activity and to make recommendations for future educational offerings, please take a few moments to complete this evaluation form. Your response will help ensure that future programs are informative and meet the educational needs of all participants.

Please note: CE credit letters and long-term credit retention information will only be issued upon receipt of completed evaluation form.

**PROGRAM OBJECTIVES:** Having completed this activity, are you better able to:

<table>
<thead>
<tr>
<th>Objective</th>
<th>Description</th>
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<th>Strongly Disagree</th>
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<tbody>
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<td>Objective 1:</td>
<td>Recognize the implications of New Jersey’s 2007 legislation on HIV testing in pregnancy to reduce perinatal HIV transmission.</td>
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<td>Objective 2:</td>
<td>Identify the 2011 updates to the Perinatal Guidelines that will have an impact on current practice.</td>
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<td>Objective 3:</td>
<td>Describe research findings that influence the 2011 Perinatal Guidelines update.</td>
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**OVERALL EVALUATION:**

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<td>The information presented increased my awareness/understanding of the subject.</td>
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<tr>
<td>The information presented will influence how I practice.</td>
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</table>

**Based on the content of the activity, what will you do differently in the care of your patients? (check one)**

- [ ] Implement a change in my practice.
- [ ] Seek additional information on this topic.
- [ ] Do nothing differently as the content was not convincing.
- [ ] Do nothing differently. System barriers prevent change.
- [ ] Not applicable. I do not see patients in my current position.

If you anticipate changing one or more aspects of your practice as a result of your participation in this activity, please provide us with a brief description of how you plan to do so.

May we contact you in two months to see how you are progressing on the changes indicated above?

- [ ] Yes. Please provide your email address. ____________________________
- [ ] No. I do not wish to participate in the follow-up assessment.

If you are not able to effectively implement what you learned at this activity, please tell us what the system barriers are (e.g., reimbursement issues, managed care rules, formulary decisions, countervailing practice guidelines, etc).

Please list any topics that you would like addressed in future educational activities.