APPENDIX H

- Human Immunodeficiency Virus (HIV)
- Virginia Legal Requirements

PREVENTION OF PERINATAL TRANSMISSION THROUGH PRENATAL TESTING AND MANAGEMENT OF HIV+ PREGNANT WOMEN

INTRODUCTION:

In 1994, after the announcement of the results of the PACTG protocol 076, the Public Health Service (PHS) published guidelines for using zidovudine to reduce Perinatal HIV transmission. In 1998, the Institute of Medicine (IOM) also recommended universal counseling and voluntary HIV testing of all pregnant women and treatment of those infected, given the effective interventions available to treat HIV-infected women and reduce risk for perinatal HIV transmission. With implementation of these recommendations by the PHS, there was a subsequent steep decline in perinatal HIV transmission. Despite this progress, children are still being infected perinatally, largely because of missed opportunities for prevention. These continued infections underscore the need for improved strategies to ensure that all pregnant women are offered HIV testing and, if positive, treatment to reduce their transmission risk and to safeguard their health and the health of their infants.

Most women with HIV/AIDS in the United States reside in the Northeast and the South. African-American and Hispanic women are disproportionately affected. In addition, the proportion of cases from heterosexual contact has increased, particularly among young women. This means that women seen in VDH Prenatal Clinics are at somewhat higher risk of possible HIV infection than in other areas of the country.

BACKGROUND INFORMATION:

Perinatal transmission can occur during pregnancy (intrauterine), during labor and delivery (intrapartum), or after delivery through breast- feeding (postpartum). An opportunity is missed whenever a woman of childbearing age is unaware of her HIV status or her risk for HIV, or when an HIV-infected pregnant woman: does not receive prenatal care, is not offered HIV testing, is unable to obtain HIV testing, is not offered chemoprophylaxis, is unable to obtain chemoprophylaxis, or does not complete the chemoprophylaxis regimen. Prevention of vertical transmission involves interventions on many fronts, including: early prenatal care, offer and acceptance of HIV testing, receipt of chemoprophylaxis, abbreviated antiretroviral regimens, cesarean delivery, follow-up of infants, and refraining from breast-feeding.

Cesarean delivery performed before onset of labor and membrane rupture lowers the risk for HIV transmission compared with vaginal delivery in certain populations of women. In 1999 and 2000, the American College of Obstetricians and Gynecologists (ACOG) recommended offering scheduled cesarean delivery at 38 weeks gestation to reduce the risk for vertical transmission of HIV infection.

TESTING GUIDELINES for Health Department Clinics:

1. HIV testing should be considered a routine part of prenatal care, and all pregnant women should be tested. Providers should recommend testing (not just passively offer it) and point out the substantial benefits of knowledge of HIV status for the health of women and their infants.

2. The testing process (consent, logistics, scheduling, etc.) should be simplified as much as possible so that pretest counseling is not a barrier to testing. Testing through Division of Consolidated Laboratory Services and procedures as recommended by VDH should be followed. When the pretest process is simplified to providing only essential information, the value of prevention counseling should not be lost. For some women, the prenatal care period could be an ideal opportunity for HIV prevention and subsequent behavior change to reduce risk for acquiring HIV infection later in life.

3. Testing should be done as early in pregnancy as possible in consenting women to promote informed and timely therapeutic decisions. Retesting in the third trimester (preferably before 36 weeks gestation) is recommended for women at high risk for acquiring HIV (e.g. those with history of STDs, who exchange sex for money or drugs, who have multiple sex partners during pregnancy, who use illicit drugs, who have HIV positive partners, or who have signs of seroconversion), but is not generally necessary for the majority of the population.

4. Informed consent before HIV testing is essential. The consent process should be flexible enough to allow for various types of informed consent. Information can be presented orally or in writing and should use language the client understands. Documentation of informed consent should be in writing.

5. HIV testing should be voluntary and free of coercion. Prenatal clinics should maintain a voluntary approach to testing that preserves a woman's right to make decisions regarding testing and supports her right to refuse testing if she does not think it is in her best interest.

6. Although HIV testing is recommended, women should be allowed to refuse testing. However, since testing is so important and highly recommended, any refusal of testing should be explored and the reasons addressed (e.g. lack of awareness of risk, fear of the disease, partner violence, potential stigma, or discrimination). This effort promotes health education and builds trust, possibly allowing for consent to testing at a future date. Anonymous testing can be offered, but women should be informed of the limitations of that process (inability to provide treatment if needed without retesting).

7. Testing procedures and interpretation of test results should be based on standard testing protocols. PHS recommends initial screening with an FDA-licensed

enzyme immunoassay (EIA) followed by confirmatory testing of repeatedly reactive EIAs with an FDA-licensed supplemental test (e.g. Western Blot). An HIV test should be considered positive only after screening and confirmatory tests are reactive.

8. HIV testing and treatment at the time of labor and delivery should be considered an option for women who are not tested during their pregnancies. Women should be informed about rapid tests for HIV that can be done at the time of delivery, and further informed that those results might be incomplete. Sensitivity and specificity of rapid assays are comparable with EIA's. However, the predictive value of a single screening test varies with the prevalence of HIV infection among the population, and thus it is more likely that the positive predictive value would be low, requiring further testing and uncertainty at the time of delivery. Again, it is better to encourage early testing rather than delaying until delivery.

GUIDELINES FOR MANAGEMENT OF HIV POSITIVE WOMEN:

1. HIV-infected pregnant women should receive HIV prevention counseling as recommended by CDC (see *Revised Guidelines for HIV Counseling, Testing, and Referral*). This counseling should include discussion of the risk for perinatal HIV transmission, ways to reduce this risk, and the prognosis for infants who become infected. Women should also be told of the clinical implications of a positive HIV antibody test and the need for early intervention services.

2. Women should be counseled regarding antiretroviral therapy during pregnancy to improve their health and prevent perinatal transmission. Pregnancy is not an adequate reason to defer therapy for HIV infection, and in fact, is generally recommended to prevent perinatal transmission.

3. Several risk factors are associated with increased risk of perinatal transmission including: immunologically or clinically advanced HIV disease in the mother, high plasma viral load, maternal injection-drug use during pregnancy, preterm delivery, failure to receive prenatal prophylaxis, and breast-feeding. HIV positive women should be counseled about these increased risks and advised to consider prophylaxis and cesarean delivery.

4. Since most Local Health Districts do not provide for direct primary care services for HIV, providers in prenatal clinics should ensure that infected women are properly referred to available specialty resources and that they initiate and adhere to recommended treatment regimens throughout their pregnancies.

5. Obstetric providers in VDH prenatal clinics should adhere to best obstetric practices, including offering scheduled cesarean section at 38 weeks to reduce the risk for perinatal transmission.

6. HIV infected women should receive information regarding all reproductive options during pregnancy and birth control methods postpartum.

7. To eliminate the risk for postnatal transmission, HIV infected women in the United States should not breast-feed. Prenatal clinic providers should reinforce this recommendation and ensure that women have adequate resources for obtaining infant formula.

8. HIV infected women should be informed of the importance of follow-up for their children, since the child's HIV status will remain uncertain until at least 18 months of age. Initial antiretroviral therapy is almost always indicated for a newborn, and in some cases, additional prophylaxis for opportunistic infections is recommended.

SUMMARY

Because of recent advances in antiretroviral therapy and prevention of perinatal transmission, it is more important than ever for women to be tested for HIV as a routine part of prenatal care. This will ensure that infected women can be identified and treated for the protection of their own health and that of their baby. VDH prenatal clinics should follow the CDC recommendations for testing and counseling and incorporate them into their local policies and procedures.

REFERENCES :

1. Public Health Service Task Force 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. HIV/AIDS Treatment Information Service (ATIS) website at <http://www.hivatis.org>. Accessed August 30, 2002.
2. CDC, Revised Recommendations for HIV Screening of Pregnant Women, MMWR 2001; 50 (No. RR-19): 63-81.
3. CDC website: www.cdc.gov/

HIV AND PREGNANCY UPDATE
ID CLINIC
TREATMENT UPDATE: HIV AND PREGNANCY

Start HIV meds 2nd trimester, but continue meds if patient is taking them prior to pregnancy. Standard care is to use 3 drugs.

Have not found any bad effects in babies born to mothers who took HIV meds during the pregnancy. AZT has been the most studied drug with HIV and pregnancy. No problems found in children so far, 4-6 years out.

Sustiva is contraindicated in pregnancy; has caused anencephaly in monkeys. If patient is taking Sustiva when she becomes pregnant, discontinue.

Combivir (AZT & 3TC) and Nelfinivir (sometimes Neviripine) most often used in pregnancy. Meds cause nausea, diarrhea, fatigue, and anemia. If the MCV and MCH value are high, but the Hgb is low, on a Heme-18, the anemia is probably related to AZT. Diarrhea is common with Nelfinivir; may use Imodium.

D14 and DDI can cause a HELLP-like syndrome, with lactic acidosis and liver toxicity, and are not used in pregnancy.

Labs to expect in pregnancy include: liver enzymes q trimester, either by Comprehensive Metabolic panel or Hepatic panel, HIV Viral Load, CD4/CD8, and Heme 18.

The pregnant woman will receive IV AZT during labor and delivery. Babies receive AZT PO for 6 weeks after delivery.

HIV Genotype is done if suspect resistance to meds.

PPROM, >4 hours, increases risk of transmission of virus to fetus.

Offer flu vaccine to all pregnant, HIV-positive patients. The vaccine may temporarily increase the Viral Load. These patients should also receive the Hepatitis vaccine to protect the liver, due to many meds.

Screen all patients for Hepatitis C, and do a Hepatitis B Convalescent panel.

If CD4 count is <2000, patient needs to be on Bactrim to prevent pneumoscystis carinii pneumonia. If CD4 count is <100, should be on Azithromycin, also.

Orasure is available, and is rapid testing for HIV. This is an oral swab, and is useful in labor, so that AZT can be given if positive.

60% of women who deliver become non-adherent to medicine regimen.

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10/8/03

Pre- and Post test H.I.V. Counseling for Pregnant Women by Prenatal Care Providers (1995)

§ 54.1-2403.01. Routine component of prenatal care.

As a routine component of prenatal care, every practitioner licensed pursuant to this subtitle who renders prenatal care, regardless of the site of such practice, shall advise every pregnant woman who is his patient of the value of testing for Human Immunodeficiency Viruses (HIV) infection and shall request of each such pregnant woman consent to such testing. The confidentiality provisions of § 32.1-36.1, the informed consent stipulations, test result disclosure conditions, and appropriate counseling requirements of § 32.1-37.2 shall apply to any HIV testing conducted pursuant to this section. Practitioners shall counsel all pregnant women with HIV-positive test results about the dangers to the fetus and the advisability of receiving treatment in accordance with the then current Centers for Disease Control recommendations for HIV-positive pregnant women. Any pregnant woman shall have the right to refuse consent to testing for HIV infection and any recommended treatment. Documentation of such refusal shall be maintained in the patient's medical record.

(1995, c. 309.)