Human Immunodeficiency Virus (HIV) (Screening, Counseling, and Preventive Medication)

Clinical Preventive Service Recommendations (Screening)

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force recommends that clinicians screen all pregnant women for HIV.[1]

Evidence Rating: **A (Strongly Recommend/Good Evidence)**

The USPSTF found good evidence that both standard and FDA-approved rapid screening tests accurately detect HIV infection in pregnant women and fair evidence that introduction of universal prenatal counseling and voluntary testing increases the proportion of HIV-infected women who are diagnosed and are treated before delivery. There is good evidence that recommended regimens of highly active antiretroviral therapy (HAART) are acceptable to pregnant women and lead to significantly reduced rates of mother-to-child transmission. Early detection of maternal HIV infection also allows for discussion of elective cesarean section and avoidance of breastfeeding, both of which are associated with lower HIV transmission rates. There is no evidence of an increase in fetal anomalies or other fetal harm associated with currently recommended antiretroviral regimens (with the exception of efavirenz). Serious or fatal maternal events are rare using currently recommended combination therapies. The USPSTF concluded that the benefits of screening all pregnant women substantially outweigh potential harms.[1]

CDC Recommendation

The Centers for Disease Control and Prevention (CDC) recommends that clinicians screen all pregnant women for HIV.[2]

- HIV screening should be a routine part of prenatal care for all women. Providers should inform all of their obstetric patients of the substantial benefit that knowledge of HIV status has for the health of a woman and her infant.
- HIV screening should occur as early as possible during pregnancy so that informed therapeutic decisions can be made and treatment can begin early. For women at high-risk of HIV infection (e.g., women who have a history of sexually transmitted infections [STIs], women who exchange sex for money or drugs, women who have multiple sex partners during pregnancy, and women who use illicit drugs during pregnancy) should be re-tested during the third trimester (at or before 36 weeks' gestation).
- Women who are admitted for labor and delivery who have not been screened for HIV or whose HIV status is unknown should be tested immediately so that timely prophylactic treatment can be initiated if appropriate. In such cases, rapid testing or the expedited return of standard testing results is recommended. After delivery, the standard confirmatory testing should be completed.
- HIV screening should be voluntary and free of coercion. Women should not be tested without their knowledge, and a woman's decision to decline testing must not have detrimental consequences for the quality of prenatal care or labor and delivery care she receives.

CDC recommends that all pregnant women receive counseling and educational information on HIV and HIV screening *before* they are screened/tested.[2]

- Information regarding HIV and the risks of HIV infection should be given to all pregnant women as a part of routine prenatal care health education.
- Pregnant women who have behaviors that place them at high risk for acquiring HIV infection (e.g., multiple sex partners, history of STIs, substance abuse, etc) should be referred to an HIV risk-reduction service (e.g., HIV centers with personnel trained in HIV counseling, drug treatment centers, etc).

Other Recommended Guidance

The U.S. Public Health Service concurs with the CDC recommendations regarding screening and counseling.

Important Screening Information

Regulations, laws, and policies regarding HIV screening of pregnant women and infants differ throughout the United States and its territories. Healthcare providers should adhere to local laws and regulations concerning maternal HIV screening.[3]

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Centers for Disease Control and Prevention (CDC)
- Peer-reviewed research
- U.S. Public Health Service (USPHS)
- U.S. Preventive Services Task Force (USPSTF)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Approximately 120,000 to 160,000 HIV infected women live in the Unites States, 80% of whom are of childbearing age.[3] Each year between 1985 and 1995, approximately 6,000 to 7,000 HIV infected women gave birth. Infected women can pass on HIV to their infants (called perinatal HIV transmission) during pregnancy, during labor and delivery, or after delivery through breastfeeding.[3]

During the early 1990s, before preventive medication was available to prevent HIV transmission from an infected pregnant woman to her infant, an estimated 1,000 to 2,000 infants were born with HIV infection each year and the risk for mother-to-child transmission ranged from 16% to 25%.[3] Widespread universal screening and perinatal use of combination antenatal antiretroviral drugs and/or zidovudine combined with cesarean section sharply reduced transmission risk and thus the number of perinatally acquired HIV infections.[3] By 2001, the perinatal transmission rate was reduced to less than 2%.[3]

However, despite important screening and treatment advances, perinatal HIV transmission continues to occur; the CDC estimates that each year in the United

States 280 to 370 infants are born with HIV.3 Most exposed infants are born to women who were not tested for HIV prenatally or whose test results were unknown at the time of delivery.[3]

Condition/Disease Risk Factors

Risk factors for perinatal HIV transmission include immunologically or clinically advanced HIV disease in the woman, a high plasma viral load, preterm delivery, injection drug use during pregnancy, and breastfeeding. The risk of perinatal transmission also increases with protracted labor after the rupture of membranes, maternal infection with a secondary STI, and the use of certain obstetrical procedures.[3]

Value of Prevention

Economic Burden of Condition/Disease

Analysis of the KIDS Inpatient Database of the Healthcare Cost and Utilization Project (HCUP) estimated that there were 4,107 hospitalizations among HIV-infected children in the United States in 2000, which accounted for approximately $100 million in hospital charges and more than 30,000 hospital days.[4]

The estimated *lifetime* health care related cost of a pediatric HIV infection is estimated to range between $100,000 and $117,000 (in year 1994 dollars). The total costs depends on how rapidly an infant's HIV progresses to AIDS and the length of his or her life.[5]

Workplace Burden of Condition/Disease

Not Provided

Economic Benefit of Preventive Intervention

The economic benefit of the preventive intervention includes the value of life years saved plus savings that accrue by avoiding the lifetime cost of managing an HIV infection.

Estimated Cost of Preventive Intervention

The cost of screening, testing, and treating HIV varies significantly, depending on where the test is administered, whether counseling is also provided, and what treatment protocol is followed. In 2004, the private-sector cost of HIV screening averaged $29 (range $4 to $90); the cost of counseling averaged $39 (range $0-to $129).[6]

Estimated Cost of Treatment

The average wholesale price (AWP) for a 1-month supply of oral zidovudine (ZDV) tablets is $219.02 (generic) or $410.54 (brand – Retrovir®).[7] The AWP for 6 weeks worth of zidovudine syrup — the recommended treatment for exposed infants — is $48.13 (generic) or $54.73 (brand – Retrovir®). Retrovir® treatment for HIV-positive women during labor/delivery is $246.71 (cost varies depending on dose, which is based on the woman's weight).[7]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

Researchers studied the costs associated with screening and treating HIV/AIDS in pregnant women and found that universal screening can be cost-saving in this population. For example, compared to no screening, a universal screening program targeting pregnant women would save an estimated $3.69 million dollars and prevent 64.6 cases of pediatric HIV infection for every 100,000 pregnant women screened.[8]

Preventive Intervention Information	
Preventive Intervention: Purpose of Screening, Counseling, and Preventive Medication	The purpose of screening is to identify infected women early in the course of pregnancy. Early identification and the administration of preventive medication can reduce perinatal transmission rates to less than 2%.[3] Counseling services are required to educate women on the benefits and risks of screening, risk reduction strategies, and, for those who screen positive, treatment options.
Benefits and Risks of Intervention	The risks associated with screening for HIV include the potential negative consequences of HIV infection such as discrimination and stigmatization, loss of relationships, domestic violence, and adverse psychological reactions such as depression or anxiety. The benefit of identification and early treatment — both necessary to prevent perinatal HIV transmission — outweigh the risks and costs associated with screening. Further, many of the aforementioned risks can be reduced through appropriate education and counseling.[3]
Initiation, Cessation, and Interval of Screening	HIV screening should occur as early as possible during pregnancy so that informed therapeutic decisions can be made and treatment can begin early. For women at high risk of HIV infection (e.g., women who have a history of STIs, women who exchange sex for money or drugs, women who have multiple sex partners during pregnancy, and women who use illicit drugs during pregnancy) should be re-tested during the third trimester (at or before 36 weeks' gestation). Women who are admitted for labor and delivery who have not been screened for HIV or whose HIV status is unknown should be tested immediately so that timely prophylactic treatment can be initiated if appropriate. In such cases, rapid testing or the expedited return of standard testing results is recommended. After delivery, the standard confirmatory testing should be completed.[2]
Counseling	Counseling should be provided before and after screening, as medically indicated.
Preventive Medication	Preventive medication should be provided, as medically indicated, to prevent perinatal transmission.
Intervention Process: Screening	Screening for HIV should be conducted with an Food and Drug Administration (FDA)-licensed enzyme immunoassay (EIA). If positive, the EIA should be followed by a confirmatory test with an FDA-licensed supplemental test such as the Western blot test. If a woman is being screened for the first-time during labor and delivery, a rapid assay test should be used in place of the EIA. A rapid test can provide a definitive negative result and a preliminary positive result, thus identifying women who could benefit from antiretroviral treatment and a cesarean delivery, and identifying infants who could benefit from antiretroviral prophylactic treatment. Rapid tests should be confirmed by a supplemental test, but, due to time constraints, suspected HIV positive women may be offered treatment before the results of the supplemental test are received. Only one FDA-approved rapid HIV test is currently available in the United States, the Abbott

Murex Single Use Diagnostic System HIV-1 test. Other tests are pending approval.[2]

Counseling

All pregnant women should receive counseling and educational information on HIV and HIV screening before they are screened.[2] Pregnant women who have behaviors that place them at high risk for acquiring HIV infection (e.g., multiple sex partners, history of STIs, substance abuse, etc) should be referred to an HIV risk-reduction service (e.g., HIV centers with personnel trained in HIV counseling, drug treatment centers, etc).[1] HIV-infected pregnant women should receive HIV prevention counseling. 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. HIV-infected pregnant women should be counseled regarding antiretroviral therapy during pregnancy to improve their health and prevent perinatal transmission.[3]

Preventive Medication

The primary strategy to prevent perinatal transmission (in addition to avoidance of breastfeeding) is antiretroviral chemoprophylaxis using zidovudine (ZDV), now often part of a combined antiretroviral therapy regimen that reduces viral load as low as possible near the time of delivery. ZDV should be administered orally to the mother during the second and third trimesters of pregnancy; intravenous administration of ZDV should be given to the woman during labor and delivery. Infants born to HIV-positive women should be given ZDV during the first 6 weeks of life.[3]

Treatment Information

Health benefits should include provisions for ongoing treatment for HIV-positive women and their infants.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: A (Strongly Recommended/Good Evidence)

- The USPSTF found good evidence to recommend that clinicians screen all pregnant women for HIV.[1]

Recommended Guidance:

The Centers for Disease Control and Prevention (CDC)
Strength of Evidence: Not Specified

- The CDC recommends that clinicians screen all pregnant women for HIV.[2]
- The CDC recommends that all pregnant women receive counseling and educational information on HIV and HIV screening before they are screened/tested.[2]
- The CDC recommends that zidovudine be administered orally to HIV-positive pregnant women during the second and third trimesters of pregnancy and

intravenously during labor and delivery. The CDC also recommends that oral ZDV be administered to exposed infant during the first 6 weeks of life.[2]

These recommendations are supported by the:

- U.S. Public Health Service

Authored by:

Lentine D, Campbell KP. Human immunodeficiency virus evidence-statement: screening, counseling, and preventive medication. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

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