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# Recommendations of the Immunization Practices Advisory Committee Prevention of Perinatal Transmission of Hepatitis B Virus: Prenatal Screening of all Pregnant Women for Hepatitis B Surface Antigen

Transmission of hepatitis B virus (HBV) from mother to infant during the perinatal period represents one of the most efficient modes of HBV infection and often leads to severe long-term sequelae. Infants born to mothers positive for hepatitis B surface antigen (HBsAg) and hepatitis B "e" antigen (HBeAg) have a 70%-90% chance of acquiring perinatal HBV infection, and 85%-90% of infected infants will become chronic HBV carriers (1,2). It has been estimated that more than 25% of these carriers will die from primary hepatocellular carcinoma or cirrhosis of the liver (3). These deaths usually occur during adulthood, when familial and financial responsibilities make them particularly devastating. In the United States, an estimated 16,500 births occur to HBsAg-positive women each year (about 4,300 of whom are also HBeAg- positive), and approximately 3,500 of these infants become chronic HBV carriers. Prenatal screening of all pregnant women would identify those who are HBsAg- positive and thus would allow treatment of their newborns with hepatitis B immune globulin (HBIG) and hepatitis B (HB) vaccine, a regimen that is 85%-95% effective in preventing the development of the HBV chronic carrier state (2,4-6).

In 1984, the Immunization Practices Advisory Committee (ACIP) recommended that pregnant women in certain groups at high risk for HBV infection be screened for HBsAg during a prenatal visit and, if found to be HBsAg-positive, that their newborns receive HBIG and HB vaccine at birth (7). No data are available regarding the proportion of high-risk women currently being screened in clinical practice, but several studies and the experience of public health workers indicate that major problems have been encountered in implementing these recommendations (8-12). These include 1) concerns about the sensitivity, specificity, and practicality of the current ACIP guidelines for identifying HBV carrier mothers; 2) lack of knowledge among prenatal health-care providers about the risks of perinatal transmission of HBV and about recommended screening and treatment procedures; 3) poor coordination among medical-care workers who provide treatment and follow-up of mothers and infants; and 4) refusal of some public and private third-party payers to reimburse for HBV screening of pregnant women and treatment of their infants. In addition, concern has been expressed that these recommendations may not be practical or applicable in some U.S. jurisdictions where HBV infection is highly endemic, such as parts of Alaska and certain Pacific Islands.

The problems encountered in implementing the currently recommended strategy of screening high-risk women have been examined by a number of investigators. Recent studies in several large inner-city hospitals, where all pregnant women were tested for HBsAg, have found that only about 35%-65% of HBsAg-positive mothers would have been identified by following the current ACIP guidelines (8-12). In these studies, the prevalence of HBsAg in inner-city black (0.4%-1.5%) and Hispanic women was higher than expected. Several investigators expressed concern that many health-care providers are too busy or may be reluctant to obtain the sexual and drug-use history necessary to identify high-risk patients for screening. In addition, persons providing health care to pregnant women often are not aware of the risks of perinatal transmission of HBV and of the recommended screening and treatment guidelines. In one study, 40% of obstetricians could name no more than two groups at high risk for HBV infection, and only 28% knew the recommended treatment for infants born to HBV carrier mothers (CDC, unpublished data).

Given these limitations, it is now evident that routine screening of all pregnant women is the only strategy that will provide acceptable control of perinatal transmission of HBV infection in the United States. Screening the approximately 3.5 million pregnant women per year for HBsAg would identify 16,500 positive women and allow treatment that would prevent about 3,500 infants from becoming HBV carriers. Recent studies also indicate that the costs and benefits of universal testing of mothers are comparable to those encountered in other widely implemented programs of prenatal and blood-donor screening (13,14). The cost of an HBsAg test ranges from an estimated \$3.50 per test in blood-bank laboratories to \$21.00 per test in private commercial laboratories. If one assumes an average screening cost ranging from \$12.00 to \$20.00 per test plus \$150.00 for the HBIG and vaccine needed to treat each infant of an HBsAg-positive mother, the cost to prevent one newborn infant from becoming a chronic HBV carrier would be between \$12,700 and \$20,700.

HBsAg testing should be done early in pregnancy when other routine prenatal testing is done. The HBsAg test is widely available and can be added to the routine prenatal "panel" of tests without requiring additional patient visits. The advantages of making HBsAg testing routine during early pregnancy include 1) the ability to identify HBV carrier mothers that is not dependent on the health-care provider's identifying high-risk women or ordering HBsAg as a special test; 2) the availability of test results before delivery so that infants can receive HBIG and vaccine without delay after birth; and 3) appropriate counseling of families before delivery (15).

Because more than 90% of women found to be HBsAg-positive on routine screening will be HBV carriers, routine follow-up testing later in pregnancy is not necessary for the purpose of screening. In special situations, such as when the mother is thought to have acute hepatitis, when there has been a history of exposure to hepatitis, or when particularly high-risk behavior such as parenteral drug abuse has occurred during the pregnancy, an additional HBsAg test can be ordered during the third trimester. Few women in populations at low risk for HBV infection will have a change in HBsAg status during subsequent pregnancies. However, because of the expected benefits of making HBsAg testing a routine part of each prenatal panel, testing should be done during each pregnancy.

Women who present for delivery without prenatal care or without medical records documenting the results of HBsAg screening should have the HBsAg test done as soon as possible after admission, since delay in administration of HBIG to infants of carrier mothers will decrease the efficacy of therapy. In the studies that demonstrated the highest efficacy (85%-95%) of combined HBIG and HB vaccine prophylaxis, HBIG was administered within 2-12 hours after birth (2,4-6). In one study in which only HBIG was used for prophylaxis, no efficacy was found if HBIG was given more than 7 days after birth, and a significant decrease in efficacy was observed if it was given more than 48 hours after birth (16). Only one-third of U.S. hospitals currently perform the HBsAg test as an in-house procedure, and many of these have technicians who are trained to do the test available on only one shift. Hospitals that cannot rapidly test for HBsAg should either develop this capability or arrange for testing to be done at a local laboratory or blood bank where test results can be obtained within 24 hours.

The commercially available HBsAg tests have an extremely high sensitivity and specificity if positive tests are repeated and confirmed by neutralization as recommended by the manufacturers of the reagent kits. Testing for other markers of HBV infection, such as HBeAg, is not necessary for maternal screening. Mothers who are

positive for both HBsAg and HBeAg have the highest likelihood of transmitting HBV to their newborns. However, infants of mothers who are HBsAg-positive but HBeAg- negative may become infected and develop severe, even fatal, fulminant hepatitis B during infancy (17,18). For this reason, HBIG and HB vaccine treatment of all babies born to HBsAg-positive women is recommended.

HBsAg-positive mothers identified during screening may have HBV-related acute or chronic liver disease and should be evaluated by a physician. Identification of women who are HBV carriers through prenatal screening presents an opportunity to vaccinate susceptible household members and sexual partners of HBV carriers, as previously recommended (19). Screening and vaccination of susceptible contacts should be done by the family's pediatrician, primary health-care provider, or the physician evaluating the clinical status of the HBsAg-positive pregnant women.

Implementation of the recommendations to prevent perinatal transmission requires maternal screening, treatment of the newborn in the hospital, and administration of subsequent doses of HB vaccine to the infant during pediatric visits at 1 and 6 months of age. This multistep process requires effective transfer of information among several groups of health-care providers, knowledge of recommended treatment, and availability of HBIG and vaccine at separate facilities. Treatment failures due to lack of communication among health-care providers can occur, especially in situations where prenatal, obstetric, and pediatric care are provided in different facilities (20). Central coordination of the treatment of these infants by city, county, or state health departments would improve the education of the health-care providers involved and increase the likelihood that proper treatment is provided.

In certain populations under U.S. jurisdiction, including Alaskan Natives and Pacific Islanders, as well as in many other parts of the world, HBV infection is highly endemic in the general population, and transmission occurs primarily during childhood (21). In such groups, universal vaccination of newborns with HB vaccine is recommended to prevent disease transmission both during the perinatal period and during childhood. Several studies have shown that HB vaccine given without HBIG will prevent 70%-85% of perinatal HBV infections and 95% of early childhood infections (22,23). In many of these areas with highly endemic HBV infection, prenatal screening is impractical because the population is isolated, laboratory facilities are not available, and/or health-care budgets and personnel are limited. In these areas, control of HBV infection can be better achieved by directing available resources into programs to vaccinate all children with HB vaccine. Programs for screening all mothers for HBsAg and providing HBIG to infants born to carrier mothers are costly and will add only modestly to disease prevention. They should be considered only after the program for universal vaccination of children has been implemented.

## RECOMMENDATIONS

All pregnant women should be routinely tested for HBsAg during an early prenatal visit in each pregnancy. This testing should be done at the same time that other routine prenatal screening tests are ordered. In special situations, such as when acute hepatitis is suspected, when there has been a history of exposure to hepatitis, or when the mother has a particularly high-risk behavior such as intravenous drug abuse, an additional HBsAg test can be ordered later in the pregnancy.

If a woman has not been screened prenatally or if test results are not available at the time of admission for delivery, HBsAg testing should be done at the time of admission, or as soon as possible thereafter. If the mother is identified as HBsAg- positive more than 1 month after giving birth, the infant should first be tested for HBsAg; if negative, the infant should be treated with HBIG and HB vaccine. Hospitals where infants are delivered should have HBsAg testing capabilities or should be able to obtain HBsAg results within 24 hours from a local laboratory.

If a serum specimen is positive for HBsAg, the same specimen should be tested again, and then the test results should be confirmed by neutralization. It is unnecessary to test for other HBV markers during maternal screening, although HBsAg- positive mothers identified during screening may have HBV-related acute or chronic liver disease and should be evaluated by their physician.

Infants born to HBsAg-positive mothers should receive HBIG (0.5 mL) intramuscularly (IM) once they are

physiologically stable, preferably within 12 hours after birth. HB vaccine, either plasma-derived (10 \*gmg per dose) or recombinant (5 \*gmg per dose), should be administered IM in three doses of 0.5 mL each. The first dose should be given concurrently with HBIG but at a different site. If vaccine is not immediately available, the first dose can be given within 7 days after birth. The second and third doses should be given 1 month and 6 months after the first. Testing the infant for HBsAg and its antibody (anti-HBs) is recommended at 12-15 months of age to monitor the effectiveness of therapy. If HBsAg is not detectable and anti-HBs is present, the child can be considered protected. Testing for antibody to hepatitis B core antigen (anti-HBc) is not useful, since maternal anti-HBc can persist for more than a year. HBIG and HB vaccination do not interfere with the routine childhood immunizations.

Household members and sexual partners of HBV carriers identified through prenatal screening should be tested to determine susceptibility to HBV infection and, if susceptible, should receive HB vaccine. Screening and vaccination of susceptible contacts should be done by the family's pediatrician, primary health-care provider, or the physician evaluating the clinical status of the HBsAg-positive pregnant women.

Obstetric and pediatric staff should be notified directly about HBsAg-positive mothers so that the neonate can receive therapy without delay after birth and follow-up doses of vaccine can be given. Hospitals, as well as state, county, and city health departments, should establish programs to educate appropriate health-care providers about perinatal transmission of HBV and its control through maternal screening, treatment of infants, and vaccination of susceptible household and sexual contacts of HBV carrier women.

Programs to coordinate the activities of those providing prenatal care, hospital- based obstetrical services, and pediatric well-baby care must be established to assure proper follow-up and treatment of infants born to HBsAg-positive mothers and other susceptible household and sexual contacts.

In populations under U.S. jurisdiction in which hepatitis B infection is highly endemic, including certain Alaskan Native and Pacific Island groups, vaccination of all newborns with HB vaccine is the most effective strategy for HB control. In these populations, such vaccination programs should be given highest priority. In areas where HBsAg screening of mothers and use of HBIG in infants born to HBV carrier mothers are not practical, the vaccination of all newborns with HB vaccine should be considered the appropriate treatment. Editorial Note: Hepatitis B vaccine is the first human vaccine that can prevent both serious chronic disease and a uniformly fatal type of cancer. These recommendations, developed in consultation with representatives of the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics, represent a major step toward control of perinatal hepatitis B transmission in the United States. Programs for universal screening of pregnant women are currently in progress in Hawaii, certain Canadian provinces, Italy, West Germany, New Zealand, Australia, and Japan. More extensive infant HB vaccination programs are in progress in Alaska, American Samoa, Korea, Taiwan, Singapore, and the People's Republic of China. A number of U.S. health-care facilities have already begun to screen all pregnant women for HBsAg.

State and local health departments can facilitate implementation of these recommendations by 1) working to assure that all women receiving prenatal care in both public and private sector programs are offered screening and appropriate treatment; 2) working to assure that costs of screening and treatment are covered by public and private third-party payers; 3) establishing programs to coordinate the transfer of information between prenatal, obstetric, and pediatric health-care providers; and 4) providing health education about hepatitis B to the public and to health-care providers. CDC will continue to work with state and local health agencies and professional associations in hepatitis B prevention and control. References

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