

EVIDENCE-STATEMENT:

HEALTHY PREGNANCY (Screening, Testing, Counseling, Immunization, and Preventive Medication)

Hepatitis B Virus (HBV) (Screening, Immunization, and Treatment)

Clinical Preventive Service Recommendations

Preventive Services
Task Force
Recommendation

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

Screening

The U.S. Preventive Services Task Force (USPSTF) strongly recommends screening for hepatitis B virus (HBV) infection in pregnant women at their first prenatal visit.¹

The USPSTF found good evidence that universal prenatal screening for HBV infection using HBsAg substantially reduces prenatal transmission of HBV and the subsequent development of chronic HBV infection. The current practice of vaccinating all infants against HBV infection and post-exposure prophylaxis with hepatitis B immune globulin administered at birth to infants of HBV-infected women substantially reduces the risk for acquiring HBV infection.¹

Immunization

The U.S. Preventive Services Task Force (USPSTF) defers to the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC) on recommendations surrounding immunization.

CDC
Recommendation

Advisory Committee
on Immunization
Practices (ACIP)

Screening

The Advisory Committee on Immunization Practices (ACIP) recommends that all pregnant women be tested routinely for hepatitis B surface antigen (HBsAg) during an early prenatal visit (i.e., first trimester) in each pregnancy, even if they have been previously vaccinated or tested. Women who were not screened prenatally, those who engage in behaviors that put them at high risk for infection (e.g., injection-drug use, having had more than one sex partner in the previous 6 months or an HBsAg-positive sex partner, evaluation or treatment for a sexually transmitted infection [STI], or recent or current injection-drug use) and those with clinical hepatitis should be tested at the time of admission to the hospital for delivery.^{2,3}

Immunization

The ACIP further recommends the hepatitis B vaccine for pregnant women at risk for hepatitis B virus infection. Pregnant women who are identified as being at risk for HBV infection during pregnancy (see list of risk factors in preceding paragraph) should be vaccinated. Pregnant women at risk for HBV infection during pregnancy should be counseled concerning other methods to prevent HBV infection.^{2,3}

Management of Exposed or Potentially Exposed Infants/Treatment

The ACIP recommends that all infants born to HBsAg-positive women should receive single-antigen hepatitis B vaccine and hepatitis B immune globulin prophylaxis (HBIG) (0.5 mL) within the first 12 hours following the birth, administered at different injection sites.^{2,3}

Women admitted for delivery without documentation of HBsAg test results should have blood drawn and tested as soon as possible after admission. While test results are pending, all infants born to women without documentation of HBsAg test results should receive the first dose of single-antigen hepatitis B vaccine (without HBIG) within 12 hours following the birth.²⁻³

A summary of guidelines for the immunization of pregnant women can be found online (www.cdc.gov/nip/publications/preg_guide.htm).

Evidence Rating:

Expert Consensus

Other Evidence-Based Recommendations
American Academy of Family Physicians (AAFP)

The American Academy of Family Physicians (AAFP) strongly recommends screening for hepatitis B virus (HBV) infection in pregnant women at their first prenatal visit.⁵

Evidence Rating: SR
(Strongly Recommended)

Good quality evidence exists which demonstrates the substantial net benefit of screening for HBV over harm; the intervention is perceived to be cost-effective and acceptable to nearly all patients.⁵

Information Sources

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

- Advisory Committee on Immunization Practices (ACIP)
- American Academy of Family Physicians (AAFP)
- Centers for Disease Control and Prevention (CDC)
- Peer-reviewed research
- 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

Over 1 million people in the United States are chronic carriers of HBV.⁴ In 2003, an estimated 73,000 new HBV infections were reported in the United States.⁴ Hepatitis infection can lead to liver disease, including liver cancer, which without treatment can result in death. Between 4,000 and 5,000 chronic carriers of HBV die each year in the United States.⁴ Hepatitis B can be treated with medications if diagnosed early, but some individuals do not respond to treatment and require liver transplants to survive.

The severity of hepatitis B infection depends on the age at which an individual becomes infected and the presence of other comorbid conditions such as alcohol abuse, HIV/AIDS, or other types of liver disease.⁶ Most adolescents and adults with acute HBV infections recover fully, but 30% of children aged 1 to 5 years

	<p>and 2% to 6% of adults become chronically infected with hepatitis B.⁷ Immunization against HBV is the single most effective way of preventing hepatitis B infection and its consequences.²</p>
<p>Condition/Disease Risk Factors</p>	<p>The risk factors for hepatitis B include intravenous drug use, concurrent infection with a sexually transmitted infection (STI), multiple sexual partners, household contact with an infected person, and being a healthcare worker with exposure to bodily fluids. However, 30% to 40% of infected individuals have no identified risk factors.⁶</p> <p>Infants can contract hepatitis B from an infected woman during labor and delivery and as many as 90% of infants infected through perinatal transmission become chronic carriers of HBV.²</p>
<p>Value of Prevention</p>	
<p>Economic Burden of Condition/Disease</p>	<p>The economic burden of hepatitis B infection depends on whether the infection is acute or chronic and what treatment is required. The direct medical cost of outpatient treatment for symptomatic acute hepatitis B has been estimated at \$272 per occurrence, while the cost of hospitalization for symptomatic hepatitis B infection is \$8,080 per occurrence (both in year 2000 dollars).⁸ If a patient develops liver disease as a result of chronic HBV infection, the direct medical cost of treatment is estimated to be \$59,308 (before discounting)⁸ and patients who require a liver transplant can have first-year billed charges of up to \$244,600 (in year 1999 dollars).⁹</p>
<p>Workplace Burden of Condition/Disease</p>	<p>HBV is also responsible for disability costs, costs associated with work-loss and absenteeism, and other indirect costs.</p>
<p>Economic Benefit of Preventive Intervention</p>	<p>Screening pregnant women for HBV, and treating the infants of HBV-positive women with post-exposure hepatitis B immune globulin prophylaxis and HBV vaccination can dramatically reduce the incidence of perinatal HBV transmission and thus the number of infants who become chronically infected with hepatitis B.² The additional recommended step of vaccinating all infants with HBV at birth also serves as a safety net to prevent perinatal hepatitis B transmission.² The averted direct and indirect costs of illness from each case of HBV prevented constitute the predominant economic benefit of the preventive intervention. From a societal perspective, prevention of perinatal HBV infection was estimated to save \$41.8 million (in year 1993 dollars) in medical and work-loss costs.¹⁰</p>
<p>Estimated Cost of Preventive Intervention</p>	<p>In 2004, the private-sector cost of¹¹:</p> <ul style="list-style-type: none"> • Screening for HBV via the hepatitis B surface antigen test averaged \$22; approximately 95% of all paid claims fell within the range of \$0 to \$64 per test. • An adult HBV vaccine averaged \$35; approximately 95% of all paid claims fell within the range of \$0 to \$77. • Vaccine administration averaged \$10; approximately 95% of all paid claims fell within the range of \$0 to \$20 (3 doses are usually needed for full protection).

<p>Estimated Cost of Treatment</p>	<p>In 2004, the private-sector cost of post-exposure hepatitis B immune globulin prophylaxis (for infants born to HBV-positive women) averaged \$178 and approximately 95% of all paid claims fell within the range of \$0 to \$514.¹¹</p> <p>The cost of therapeutic treatment of chronic hepatitis B varies according to the medication required; a single course of interferon therapy costs \$5,570 including provider visits and laboratory costs (in year 1995 dollars).¹²</p>
<p>Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention</p>	<p>The estimated cost of preventing a perinatal HBV infection is \$164 per year of life saved, (in year 1993 dollars).¹⁰ In comparison to other preventive interventions and to commonly accepted cost-effectiveness benchmarks, hepatitis B screening is highly cost-effective.</p>
<p>Preventive Intervention Information</p>	
<p>Preventive Intervention: Purpose of Screening and Immunization</p>	<p>Screening pregnant women for HBV, immunizing women at high-risk of HBV, and treating the infants of HBV-positive women with post-exposure hepatitis B immune globulin prophylaxis and HBV vaccination, can dramatically reduce perinatal HBV transmission and, thus, the number of infants who become chronically infected with hepatitis B.²</p>
<p>Benefits and Risks of Intervention</p>	<p>The benefits of screening, immunization, and treatment are substantial; an untreated maternal hepatitis B viral infection may result in severe disease for the woman and chronic infection for the newborn.²</p> <p>There is no apparent risk of adverse effects for developing fetuses when a hepatitis B vaccine is administered to a pregnant woman.³</p>
<p>Initiation, Cessation, and Interval Screening</p>	<p>Screening for hepatitis B should be conducted at the first prenatal visit in each pregnancy. Women at increased risk of acquiring HBV may be screened again during the third trimester and/or during labor and delivery and should be offered the hepatitis B vaccine. Household contacts of women with a positive HBsAg test should also be screened for HBV infection. Women admitted for delivery without documentation of HBsAg test results should have blood drawn and tested as soon as possible after admission.²</p>
<p>Immunization</p>	<p>HBV immunization should be given to high-risk pregnant women as deemed appropriate by the clinician.²</p> <p>All infants should receive their first hepatitis B immunizations at the time of birth. Infants born to HBV-infected women should be immunized and given immune globulin within 12 hours of birth. Infants born to women with unknown HBsAg status should receive one dose of single-antigen hepatitis B vaccine (without HBIG) within 12 hours of birth, while awaiting the woman's test results.²</p>
<p>Treatment</p>	<p>Post-exposure hepatitis B immune globulin prophylaxis should be given, as medically indicated.²</p>

Intervention Process Screening	The principal screening test for detecting an HBV infection (acute or chronic) is the identification of HBsAg in the blood. Testing methods include the HBsAg Immunoassay and the “rapid test,” an assay that detects HBsAg and the hepatitis B e-antigen HBeAg simultaneously.
Immunization	HBV immunizations are administered via injection.
Treatment	Post-exposure hepatitis B immune globulin prophylaxis.
Treatment Information	Please refer to the “Intervention Process” section for information on preventive treatment.

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:

The U.S. Preventive Services Task Force (USPSTF)

Strength of Evidence: A (Strongly Recommended/Good Evidence)

- The USPSTF found good evidence that universal prenatal screening for HBV infection using HBsAg substantially reduces prenatal transmission of HBV and the subsequent development of chronic HBV infection. The current practice of vaccinating all infants against HBV infection and post-exposure prophylaxis with hepatitis B immune globulin administered at birth to infants of HBV-infected women substantially reduces the risk for acquiring HBV infection.¹

The American Academy of Family Physicians (AAFP)

Strength of Evidence: SR (Strongly Recommended)

- AAFP strongly recommends screening for hepatitis B virus (HBV) infection in pregnant women at their first prenatal visit.⁵ Good quality evidence exists which demonstrates the substantial net benefit of screening for HBV over harm; the intervention is perceived to be cost-effective and acceptable to nearly all patients.⁵

Recommended Guidance:

The Advisory Committee on Immunization Practices (ACIP)

Strength of Evidence: Expert Consensus

Screening

The ACIP recommends that all pregnant women be tested routinely for HBsAg during an early prenatal visit (e.g., first trimester) in each pregnancy, even if they have been previously vaccinated or tested. Women who were not screened prenatally, those who engage in behaviors that put them at high risk for infection (e.g., injection-drug use, having had more than one sex partner in the previous 6 months or an HBsAg-positive sex partner, evaluation or treatment for a sexually transmitted infection [STI], or recent or current injection-drug use) and those

with clinical hepatitis should be tested at the time of admission to the hospital for delivery.^{2,3}

Immunization

The ACIP recommends the hepatitis B vaccine for pregnant women at risk for hepatitis B virus infection.

This recommendation is supported by:
The U.S. Preventive Services Task Force (USPSTF)

Management of Exposed Infants/Treatment

The ACIP recommends that all infants born to HBsAg-positive women should receive single-antigen hepatitis B vaccine and HBIG (0.5 mL) within 12 hours of birth, administered at different injection sites.²

The ACIP recommends that all infants born to women without documentation of HBsAg test results should receive the first dose of single-antigen hepatitis B vaccine (without HBIG) within 12 hours of birth, while the woman's test results are pending.²

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Campbell KP, Lindley MC, Lentine D, Bhatt A. Hepatitis B virus evidence-statement: screening, immunization, and treatment. 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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Hepatitis B Virus (Screening and Immunization)

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