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eViralHepatitis Review
May 2011: VOLUME 1, ISSUE 3

SCREENING FOR HEPATITIS B VIRUS INFECTION IN AT-RISK INDIVIDUALS

In this Issue...

Many physicians in primary care practice do not possess sufficient knowledge about hepatitis B virus (HBV) infection and screening methods. Often, primary care providers are unaware of the diagnostic screening techniques available to test for the disease. In this issue, we review the rationale for HBV screening, the serologic testing involved, and the optimal implementation of these tests in clinical practice.

LEARNING OBJECTIVES

After completing this activity, participants will demonstrate the ability to:

- Explain the necessity of screening for hepatitis B virus (HBV) infection
- Select the appropriate patient populations for HBV testing
- Interpret the results of HBV serologic tests

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THIS ISSUE

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COMMENTARY

Many primary care physicians (PCPs) are not knowledgeable about hepatitis B virus (HBV) screening. According to a 2007 survey of 196 PCPs attending a continuing medical education (CME) meeting, more than half (55%) could not identify the appropriate test to use to diagnose chronic hepatitis B (CHB), and 44% did not know that CHB could be medically treated.[1]

The rationale for hepatitis B virus (HBV) screening is multifaceted. Chronic hepatitis B (CHB) is a common condition that can be detected by an inexpensive, accurate test. Although treating CHB can prevent the long-term complications of cirrhosis and hepatocellular cancer, treatment cannot be effective unless the infection has been diagnosed. Because CHB is usually clinically silent, approximately two-thirds of individuals with the disease are unaware of their infections.[2] Additionally, HBV testing has been shown to be cost-effective in populations with intermediate to high disease prevalence (that is, ≥2%).[3] Thus, screening for HBV infection is medically and economically justifiable and is recommended by all relevant guidelines.[4-6]

The first step in HBV screening is to detect patients with risk factors for the disease. Universal HBV testing is not recommended. Instead, screening is recommended order to identify specific groups of patients who are most likely to benefit from serologic testing. Table 1 lists patient populations for whom HBV testing is recommended.

Table 1. Patient populations for whom HBV testing is recommended[4,5]

Persons born in geographic regions with an HBsAg prevalence ≥2%
Infants born to infected mothers
Household contacts and sexual partners of persons with CHB
IV drug users
Sexually active persons not in long-term, mutually monogamous relationships
Men who have sex with men
Health care and public safety workers at risk for occupational exposure
Residents and staff of facilities for developmentally disabled persons
Persons with chronic liver disease
Patients undergoing hemodialysis
Travelers to countries with an intermediate or high prevalence of HBV
Patients with HIV infection

CHB, chronic hepatitis B; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HIV, human immunodeficiency virus; IV, intravenous.

Most of the groups recommended for HBV testing have a CHB prevalence of ≥2%, which is considerably higher than that of the general population at <1%. Key among these groups are immigrants from Asia and the Pacific Islands, in whom the prevalence of CHB is approximately 10%. In one study, HBV serologic testing was offered to 3163 Asian American adult volunteers in the San Francisco area between 2001 and 2006.2 Of those tested, 8.9% had CHB and 65.4% of those were unaware of their infection. Those born outside the United States were 19.4 times more likely to have CHB. Similar results have been reported from other metropolitan areas.[6]

Testing is recommended in some patients because of a specific opportunity to prevent HBV transmission or disease complications. For example, all pregnant women should be tested for CHB, as perinatal transmission can be prevented by aggressive management of the newborn. Moreover, patients who plan to receive immunosuppressive agents should also be tested for CHB because of a 20% to 50% likelihood of a disease flare-up either during or immediately after immunosuppression.[8] All patients infected with HIV should be tested as well, both because their risk for CHB is high and because some medications are active against both viruses, rendering it important to be aware of dual infection.

Routine serologic testing for CHB should include testing for the hepatitis B surface antigen (HBsAg) and antibodies to hepatitis B surface antigen (anti-HBs). Use of these two tests provides a simple algorithm (Figure 1). Since at-risk individuals are generally tested, those with negative results for both markers should be vaccinated against HBV. Those with a positive test for anti-HBs are immune to the disease and can be reassured that they do not have HBV and are protected, because of either a prior infection or to previous immunization. People with positive HBsAg tests may have CHB and may require medical management. An essential part of that management is testing all household contacts and sexual partners and providing HBV vaccination to those who are at risk.

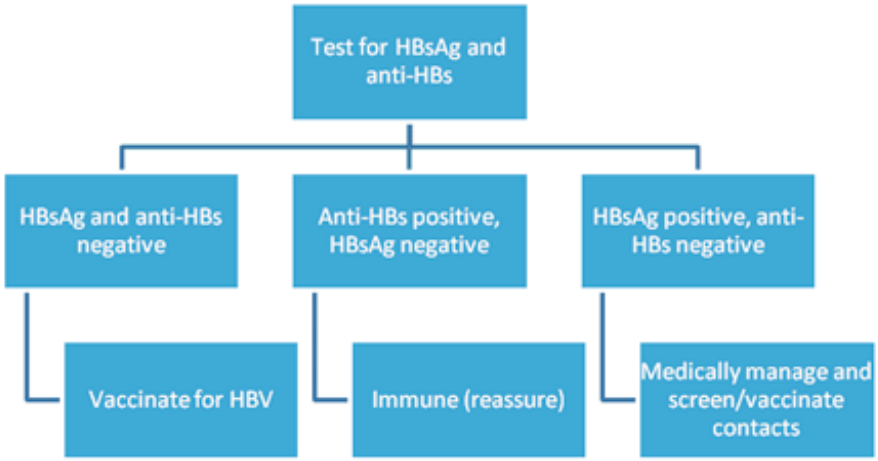

Figure 1. Isolated antibody to hepatitis B core antigen and other test outcomes
Anti-HBs, antibodies to hepatitis B surface antigen; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus.

Some laboratories offer serologic panels that include other tests, such as antibodies to the hepatitis B core antigen (anti-HBc), hepatitis B e antigen (HBeAg), and antibodies to HBeAg (anti-HBe). Anti-HBc is detected after HBV infection but not after vaccination. Thus, anti-HBc can indicate prior resolved infection or CHB. Typically, with resolved infection, anti-HBc is detected along with anti-HBs; whereas in patients with CHB, anti-HBc is detected along with HBsAg. However, occasionally anti-HBc is detected without the presence of either anti-HBs or HBsAg. Such a serologic profile can represent a state of low-level HBV infection known as "occult hepatitis B," or it may represent a false-positive anti-HBc test result. The former is more likely to occur in persons at high risk for HBV infection, such as those with CHB or HIV; whereas the latter is more often the explanation in low-risk patients, such as those undergoing testing for life insurance. HBV vaccination can be administered to persons with isolated anti-HBc, and some experts will also test for HBV DNA, HBeAg, and anti-HBe.

Like HBsAg, HBeAg is a viral protein whose presence in the blood indicates ongoing HBV infection. HBeAg is cleared before HBsAg, and thus test results can be negative even in persons who have HBsAg in their bloodstream—a state that is referred to as e antigen-negative CHB.

Ideally, HBV screening will be incorporated into the routine of a primary care practice. However, there may be insufficient time during a routine PCP visit to screen for HBV risk factors and to follow dozens of other guidelines as well. In addition, patients may be reluctant to disclose past behaviors that place them at risk for HBV. Thus, it best to use a nonthreatening method to identify patients who might benefit from HBV testing. Inclusion of risk groups in questionnaires completed by patients before a medical visit, simple checklists, and other methods have been examined. The guidelines for HBV testing and vaccination practices are sufficiently clear to be ideal quality assurance measures. Ultimately, all providers must determine the best way to screen for CHB in their practices, and then implement the procedure, and monitor its effectiveness.

Commentary References

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ROUTINE SCREENING FOR HBV INFECTION AMONG ASIAN AMERICANS

Lin SY, Chang ET, So SK. **Why we should routinely screen Asian American adults for hepatitis B: a cross-sectional study of Asians in California.** *Hepatology*. 2007;46(4):1034-1040.

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CHB infection has long been recognized as a major public health problem in Asia. Many physicians feared that Asian Americans were also at high risk for CHB, and a wealth of indirect evidence has supported that concern. More than two-thirds of Asian Americans living in the United States are foreign-born, and in Asia, most HBV infections occur at birth or in early childhood. In addition, CHB is the leading cause of liver cancer worldwide, and liver cancer is the second leading cause of cancer mortality among Asian American men. To investigate the prevalence of CHB in Asian Americans, Lin and colleagues examined a wide range of Asian Americans in the San Francisco Bay area.

Between 2001 and 2006, free HBV testing and counseling were provided to more than 3000 Asian American adults in this region. Individuals learned about the program through Chinese and English language advertisements and were screened at community-based events, including street fairs, cultural festivals, and clinics held at churches and other community venues, as well as at the Stanford Hospital.

Of 3163 Asian American adults tested, 8.9% had CHB, and 185 of 283 (65.4%) did not know they had HBV infection. Thus, the prevalence of previously unrecognized CHB was 6.2%. Persons who were foreign-born were nearly 20-fold more likely to have CHB than were those born in the United States. In addition, males were more likely than females to have CHB, and persons with a family history of HBV were more likely to have CHB than were those with no family history. Almost half of all individuals who did not have CHB remained susceptible to the infection based on serologic testing.

This study confirmed the hypothesis that Asian Americans who are foreign-born have a markedly increased prevalence of CHB. The results support guidelines for HBsAg testing in all persons born in HBV- endemic regions of the world (defined as areas having an HBsAg prevalence of ≥2%). One of the strengths of this study was the degree to which the investigators could penetrate into various Asian American communities. There was broad public support for their campaign, which might be more difficult to replicate in areas with a lower overall density of people of Asian descent. This consideration raises the question of how to replicate the methods in other areas of the country and the degree to

which individual practitioners can expand testing beyond their practices. However, it is noteworthy that subsequent investigations conducted in other metropolitan regions of the United States have reported similar high CHB prevalences among foreign-born Asian Americans, as well as people emigrating from sub-Saharan Africa.

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COST-EFFECTIVENESS OF HBV SCREENING/VACCINATION OF ASIANS AND PACIFIC ISLANDERS

Hutton DW, Tan D, So SK, Brandeau ML. **Cost-effectiveness of screening and vaccinating Asian and Pacific Islander adults for hepatitis B**. *Ann Intern Med.* 2007;147(7):460-469.

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Significant progress has been achieved in controlling HBV infection. The recombinant vaccine is one of the safest, most effective immunizations available. The vaccine has been associated with a dramatic decline in the incidence of HBV infection in the United States, where reliable, inexpensive tests are available for detecting the disease and where new treatments can safely curb symptoms of the infection. One remaining, ongoing challenge, however, is the optimal strategy for managing HBV infection among Asian and Pacific Islander adults—the very population with the highest burden of disease. In 2007, Hutton and coworkers examined the cost-effectiveness of four possible alternatives to the status quo of voluntary screening.

The investigators used a Markov model in which a hypothetical cohort of 10,000 Asian and Pacific Islander adults was allocated to either the status quo (voluntary screening) or to 1 of 4 escalating strategies: (1) vaccinate all; (2) test and treat (i.e., all subjects undergo HBsAg testing and treatment according to current guidelines); (3) test, treat, and ring-vaccinate; and (4) testing-based management: (i.e., all subjects undergo HBsAg and anti-HBs testing to determine whether they have CHB or require vaccination, then treat and vaccinate as needed). The authors then offered reasonable assumptions about the costs of these interventions; the likelihood of possible outcomes, including the test results; the natural history of the infection, and the effectiveness of the vaccination and treatment interventions; and the costs associated with medical consequences such as liver cancer. Sensitivity analyses explored the extent to which the assumptions offered for each of these measures might affect the results. The costs were then correlated with the benefits by calculating the quality-adjusted life-years (QALYs), and that index was then compared with other “accepted” medical procedures.

According to this analysis, the main health benefits are derived from the testing and treatment of people with CHB. The costs associated with the strategies of test and treat, and of test, treat, and ring-vaccinate, are approximately $38,000 per QALY. Moreover, vaccination did not have a marked impact on patient outcomes, since the incidence of new HBV infection is already relatively low in this type of adult population, and it is expected that many of those new infections would be self-limited. The authors concluded that the strategy of testing Asian and Pacific Islander populations for HBsAg and providing treatment based on current guidelines was cost-effective.

The results of this study support most guidelines for HBV management. Guidelines endorsed by the Centers for Disease Control and Prevention (CDC), the American Association for the Study of Liver Diseases, and the Infectious Diseases Society of America all recommend HBsAg testing of Asian and Pacific Islander populations and other high-risk adults. As treatments become more effective and safer, the clinical benefits should improve accordingly.

One challenge that remains is, the costs of care in the United States are sometimes incurred by persons other than those who might experience the savings. Moreover, the cost savings sometimes require long-term projections that exceed the expectations of

even some managed care organizations. Nonetheless, among health care professionals, it is clear that people with an expected high prevalence of CHB should be tested for HBsAg, and this study provides a sound economic justification for doing so.

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SEROLOGIC FOLLOW-UP OF ISOLATED HBV CORE ANTIBODY IN WOMEN WITH AND WITHOUT HIV INFECTION

French AL, Lin MY, Evans CT, et al. **Long-term serologic follow-up of isolated hepatitis B antibody in HIV-infected and HIV-uninfected women.** *Clin Infect Dis*. 2009;49(1):148-154.

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One of the most common serologic tests for HBV infection is detection of antibodies to hepatitis B core antigen (anti-HBc). Anti-HBc is an indicator of HBV infection that can be acute (generally, when the immunoglobulin M [IgM] isotype is detected), chronic (when detected over =6 months with HBsAg), or remote (when detected along with antibodies to HBsAg). Sometimes anti-HBc is the only serologic marker detected—a condition that is referred to as isolated anti-HBc or occult hepatitis B. Many experts prefer the former, because only some instances of isolated anti-HBc represent true HBV infection. In others, the test results are false-positive. Occult hepatitis B can be diagnosed when HBV DNA is detected, when there is an anamnestic response to HBV vaccination, or with the subsequent development of another serologic marker without interval exposure. It is more difficult to prove that the results of a test are false-positive, but such an interpretation is favored in persons at low-risk with low anti-HBc titers and undetectable HBV DNA levels.

Using a long-term cohort of women at high risk for HBV, French and coworkers examined the natural history of persons with isolated anti-HBc. The investigators evaluated 322 women who enrolled at 1 of the participating sites of the Women's Interagency HIV Study, had isolated anti-HBc at study entry, and underwent ≥1 follow-up test >2.5 years later. A total of 40 women were HIV-negative, whereas 282 were HIV-infected. The median time between testing was 7.5 years. A majority of the participants (71%) were still anti-HBc-positive only; anti-HBs was detected along with anti-HBc in 20% of the women; only 2% of the subjects acquired HBsAg. Those with hepatitis C virus (HCV) infection were more likely to sustain isolated anti-HBc serology. An interesting comparator group comprised 324 women with no HBV serologic markers at baseline, and similar follow-up and risk profiles. Of the 324 women, 250 (77%) remained seronegative; 1 became HBsAg-positive with anti-HBc; 13 (4%) acquired both anti-HBc and anti-HBs; 56 acquired anti-HBs only; and 1 acquired anti-HBc only.

The long-term results of this study provide a more complete picture of what a clinician might expect to see in patients with isolated anti-HBc serologic testing. Although the majority of patients will remain stable, a small proportion may develop evidence of CHB. In the current study, it was impossible to determine whether those patients with CHB had a recrudescence of prior HBV infection or another exposure. This question, however, is at the center of the decision whether persons with isolated anti-HBc should receive HBV vaccination. According to the authors, HBV vaccination should be administered to persons with isolated anti-HBc and risk factors for ongoing exposure and/or without ongoing HCV infection (a marker of stable isolated anti-HBc). Vaccination is certainly not harmful and may be the most conservative measure, along with repeated testing, if there is any indication of high-risk exposure or unexplained elevations in liver enzymes. One guaranteed way to avoid the dilemma involved in managing patients with isolated anti-HBc is not to use the test. Some authorities recommend testing for HBsAg and anti-HBs alone, and then vaccinating those who lack anti-HBs.

The take-home message from this study is that, even in a very high-risk setting, HBV vaccination and repeat serologic testing may be indicated for those with ongoing risk, and most persons with isolated anti-HBc serology will remain stable.

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REACTIVATION OF HBV INFECTION FOLLOWING CHEMOTHERAPY

Lee R, Vu K, Bell CM, Hicks LK. **Screening for hepatitis B surface antigen before chemotherapy: current practice and opportunities for improvement.** *Curr Oncol*. 2010;17(6):32-38.

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HBV infection can be reactivated after chemotherapy. Incidence rates of reactivation vary from <10% to 73%, attributable most likely to differences in the degree of immunosuppression, the definition of HBV infection, and the rigor of ascertainment. Routine testing for HBsAg in patients undergoing chemotherapy is recommended by the CDC, but not by the American Society for Clinical Oncology (ASCO). Lee and associates compared the frequency of HBsAg screening with other "routine" precancer testing.

The investigators conducted a retrospective electronic chart review to identify the frequency of HBsAg testing of patients who began intravenous chemotherapy between March 2006 and March 2007 (before ASCO's recommendation against testing). The frequency of testing of left ventricular (LV) function before chemotherapy with cardiac toxicity was the comparator. Of 208 patients started on chemotherapy, only 28 (14%) were tested for HBsAg, whereas all patients underwent LV function testing. HBsAg testing was conducted more routinely if the person was undergoing treatment for a hematologic malignancy (38%), compared with those being treated for solid tumors (7%). The overall quality assurance goal for HBsAg testing was 90%.

An intervention was then performed to educate the team. That measure was associated with an increase in HBsAg testing of 31% and the detection of 1 new chronic carrier. Several factors seemed to reduce the use of HBsAg testing, including clerical errors, unintended omissions, and misunderstandings about the test and its benefits. Interestingly, the institution had a system to ensure that certain prechemotherapy tests were conducted. That list, checked by the pharmacist before dispensing the drug(s), included cardiac function testing but not HBsAg testing.

This study underscores many of the challenges associated with HBV testing. Testing is not routine and can be omitted both intentionally and accidentally. Using cardiac testing as the comparator is interesting for several reasons. The universal adoption of cardiac testing demonstrated a system with multiple checks for preventing unintentional omission of testing, as well as broad acceptance of its importance. One argument against the use of routine HBsAg testing is that few persons were found to be HBV-positive, and the added effort involved in testing might delay chemotherapy or add to the overall cost of health care. Interestingly, cardiac abnormalities also occurred infrequently, and the cost of the procedure and its time requirement were both substantially higher than with HBsAg testing.

The results of this review also echo some of the challenges associated with HBV testing in general. Some omissions of testing are intentional (i.e., health care providers do not believe testing is indicated). However, far more omissions appear to be accidental (ie, testing is either not considered or is ordered incorrectly). Although the primary focus of this review is HBsAg testing in oncology practice, the take-home point for primary care practitioners might be to adopt a system of provider-independent checks for routine screening practices (such as that done for cardiac testing), to maximize overall patient outcomes.

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