CD Summary

January 31, 2012
Vol. 61, No. 3

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HEPATITIS B VACCINATION FOR PATIENTS WITH DIABETES

Hepatitis B is a bloodborne and sexually transmitted, vaccine-preventable viral infection. It causes acute hepatitis, chronic hepatitis, cirrhosis and hepatocellular carcinoma.[1] Since 1996, a total of 29 outbreaks of HBV infection in long-term-care (LTC) facilities in the U.S. were reported to CDC; of these, 25 (86%) involved adults with diabetes mellitus (DM) receiving assisted blood glucose monitoring.[2] These outbreaks prompted the Advisory Committee on Immunization Practices (ACIP) to evaluate the risk for HBV infection among all adults with diagnosed diabetes. This past October, ACIP recommended that all previously unvaccinated adults aged 19–59 years with DM (type 1 and type 2) be vaccinated against hepatitis B as soon as possible after the diagnosis of diabetes is made. The data for those ≥60 years old are less robust, and ACIP took no position on whether or not they should be vaccinated.[3] This issue of the *CD Summary* will help you decide whether you should recommend HBV vaccination to your diabetic patients.

HBV: HIGHER RATES IN DM

In addition to the reported LTC outbreaks, ACIP also considered data from 865 cases of acute HBV infection reported during 2009–2010 from eight Emerging Infections Program (EIP) sites (Oregon being one of them) that together make up about 17% of the U.S. population.[4] The analysis was restricted to persons aged ≥23 years, because anyone younger was born in the era of universal HBV vaccination. In multivariable analyses that considered persons without the usual hepatitis B–related risk behaviors,* persons 23–59 years of age with diabetes had 2.1 (95% confidence interval [CI], 1.6–2.8) times the odds of developing acute hepatitis B as those without diabetes; the odds were 1.5 (CI = 0.9–2.5) for persons ≥60 years of age.

ACIP also reviewed data from the National Health and Nutrition Examination Survey (NHANES), a nationally representative sample of the non-institutionalized U.S. population. NHANES sends teams to 15 U.S. counties per year, the probability of a given county's selection being proportional to its population. The teams conduct in-home surveys and a variety of clinical testing (blood, urine, bone densitometry, et al.) in their Mobile Examination Centers.† NHANES currently recruits ~10,000 subjects per year. During 1999–2010, NHANES found the seroprevalence of antibody to hepatitis B core antigen — which indicates past or present HBV infection — to be 60% higher among persons aged ≥18 years with diagnosed diabetes compared with those without diabetes ($P<0.001$). Stratified by age, the estimated prevalence ratios were 1.7 (CI = 1.3–2.2) for persons aged 18–59 years and 1.3 (CI = 1.0–1.6) for those aged ≥60 years (CDC, unpublished data, 2011).

HBV: WORSE WITH DM

Diabetes is bad for the liver. Even *without* HBV, diabetes doubles one's risk for chronic nonalcoholic steatohepatitis and hepatocellular carcinoma, making the prevention of additional insult to the liver more important for those with DM.[5] EIP data for 2009–2010 suggested a higher case-fatality rate among persons with acute hepatitis B who had diabetes compared to those without diabetes, although the difference was not statistically significant (5% versus 2%, $P=0.13$).[3] For those who survive the acute phase, hepatitis B becomes chronic in approximately 5% of otherwise healthy adults. Hep B chronicity may be more likely among older adults with diabetes: in one hospital outbreak, 9 (45%) of 20 persons with DM who acquired HBV from a contaminated fingerstick device became chronic carriers.[6]

ROUTES OF INFECTION

HBV is highly infectious and can persist for ≥7 days on environmental surfaces at room temperature. HBV can be transmitted by blood-contaminated medical equipment — even by blood invisible to the unaided eye. Percutaneous exposures to HBV can occur as a result of assisted monitoring of blood glucose and other procedures involving instruments shared between patients.[7] Lapses in infection control during assisted blood glucose monitoring that have led to HBV transmission include multipatient use of fingerstick devices designed for single-patient use and inadequate disinfection and cleaning of blood glucose monitors between patients. Diligent adherence to infection control practices will prevent this route of transmission of HBV and of other potentially blood-borne pathogens as well. That said, guidelines for safe blood glucose monitoring have been available since 1990, and, yet, these outbreaks continue to occur: hence, the call for improved design and labeling of blood glucose monitoring devices, and for hepatitis B vaccination.

DM AND RESPONSE TO HB VACCINATION

At younger ages, the immune response to vaccine is similar among adults with and without diabetes. The proportion of adults who achieve seroprotection (≥10 mIU/mL antibody to hepatitis B surface antigen) after receipt of the 3-dose vaccine series decreases with age, obesity, smoking, immunosuppression, and comorbid conditions including diabetes (Table, *verso*). According to CDC, the 3-dose hepatitis B vaccine series generates protective antibody titers in ≥90% of diabetic adults <40 years of age, but immunologic responses drop off significantly with age (Table). Bottom line: the sooner you vaccinate, the bet-

* Injection-drug use, male sex with a male, or sex with multiple partners.

† a.k.a. trailers. See www.cdc.gov/nchs/nhanes/hlthprofess.htm.

The **CD Summary** (ISSN 0744-7035) is published fortnightly free of charge, by the Oregon Health Authority, Office of Communicable Disease and Epidemiology, 800 NE Oregon St., Portland, OR 97232
Periodicals postage paid at Portland, Oregon.
Postmaster—send address changes to:
CD Summary, 800 NE Oregon St., Suite 730, Portland, OR 97232

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PERIODICALS POSTAGE **PAID** Portland, Oregon

Oregon Health Authority

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Table. Estimated antibody responses among adults with diabetes, by age.

Age (years)	Proportion with protective antibody response§
≤40	>90%
41–59	80%
60–69	65%
≥70	<40%

§ Defined as ≥10 mIU/mL antibody to hepatitis B surface antigen [anti-HBs])

ter, and hence the recommendation to begin the series as soon as a diagnosis of DM is made.

IS IT WORTH IT?

Hepatitis B is one of the more expensive vaccines: 3 doses are required, each costing about $27, plus administration costs.‡ How do we gauge whether the expense is justified by the benefit? ACIP reviewed economic models that incorporated the costs and benefits of vaccination. They considered the efficacy of the vaccine in different age cohorts as well as the fact that immunization at younger ages may be more likely to prevent the serious sequelae — cirrhosis, hepatocellular carcinoma — that ensue only after years of chronic, smoldering infection with HBV. The analysis yielded age-stratified estimates of the incremental cost of vaccinating adults with diabetes per quality-adjusted life-year (QALY) saved. Results: the younger the age at vaccination, the cheaper it is to save a QALY; and with increasing age, the lower vaccine efficacy and diminished chance for preventing chronic sequelae lessen the likelihood that vaccinating a given patient will save a QALY. The cost per QALY saved was estimated at $75,100 for persons aged 20–59 years. With benefits considered over a patient's lifetime, a one-time vaccination program consisting of a 3-dose series of hepatitis B vaccine, given to 10% of unvaccinated U.S. adults 20–59 years of age with diagnosed diabetes (approximately 528,047 persons) would be expected to prevent 4,271 HBV infections, 467 hospitalizations, 256 chronic cases, 33 cases of hepatocellular carcinoma, 13 liver transplants, and 130 deaths. Postvaccination serologic testing and revaccination of the nonimmune would add considerable cost, with limited benefit in terms of disease prevention (CDC, unpublished data, 2011).

Within the 20–59 -year-old cohort, the cost per QALY saved rose dramatically by age; but it became truly eyebrow-raising at older ages. Collectively, for persons ≥60 years of age, it was estimated at $27 million per QALY.

ACIP RECOMMENDATIONS

On the basis of available information about HBV risk, morbidity and mortality, available vaccines, age at diagnosis of diabetes, and cost-effectiveness, ACIP recommended the following:

- Hepatitis B vaccination *should* be administered to unvaccinated adults with diabetes mellitus who are aged 19 through 59 years.
- Hepatitis B vaccination *may* be administered at the discretion of the treating clinician to unvaccinated adults with diabetes mellitus who are aged ≥60 years.

FOR MORE INFORMATION

Additional information on safe blood glucose monitoring is available at *www.cdc.gov/injectionsafety/meetings/stickingwsafety52010.html*.

Oregon hepatitis data can be found at *http://public.health.oregon.gov/DiseasesConditions/DiseasesAZ/Pages/disease.aspx?did=65*.

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‡ CDC cites a price tag of $52.50/dose for the private sector. The federal contract price for CDC grantees is $27.33. See *www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm*