

Advisory Committee on Immunization Practices (ACIP) Recommendation for Hepatitis B Vaccination for Adults with Diabetes

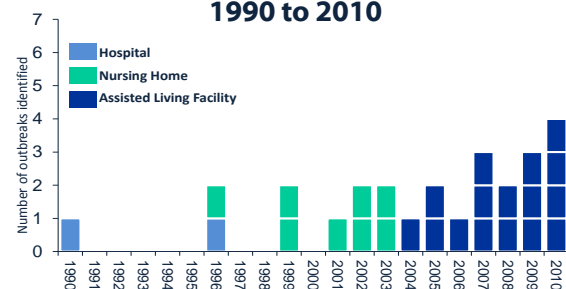
Sarah Schillie, MD, MPH, MBA, Kathy Byrd, MD, MPH, Trudy V. Murphy, MD

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Background

- Outbreaks of Hepatitis B Virus (HBV) associated with assisted blood glucose monitoring in long-term care facilities prompted the Hepatitis Work Group to assess:
 - Risk of HBV among adults with diabetes (including those not in long-term care)
 - HBV-related morbidity/mortality
 - Infection control practices
 - Hepatitis B vaccine immune response by age and diabetes status

Outbreaks of HBV Infection Associated with Blood Glucose Monitoring — United States, 1990 to 2010



Elevated Risk for HBV Infection among Adults with Diabetes Aged ≥23 Years

Age (years)	Emerging Infections Program, 2009-2010 (Odds ratio, 95% CI)	National Health and Nutrition Examination Survey, 1999-2010 (Prevalence ratio, 95% CI)
23-59*	2.1, 1.6 – 2.8	1.7, 1.3 – 2.2
≥60	1.5, 0.9 – 2.5	1.3, 1.0 – 1.6

*Age 18-59 years for NHANES

Grading of Recommendations Assessment, Development, and Evaluation (GRADE)

“Should hepatitis B vaccine be recommended for routine use among adults with diabetes?”

Work Group Values for Preventing Hepatitis B Outcomes

Outcome	<60 years	≥60 years
Acute hepatitis	High	Moderate
Fulminant hepatitis	High	High
Chronic hepatitis	High	Moderate
Cirrhosis	High	Moderate
Hepatocellular carcinoma	High	Moderate
Liver transplantation	High	Moderate
Death	High	High
Vaccine cost effectiveness	Moderate	High
Personnel time to obtain consent for vaccination	Moderate	Moderate
Pain from vaccination	Low	Moderate

Estimated Burden of HBV Prevented with 10% Vaccine Uptake

Age	Infected	Hospitalizations	Chronic cases	Cirrhosis	Deaths
20-59	4,271	467	256	202	130
≥60	723	79	43	22	11

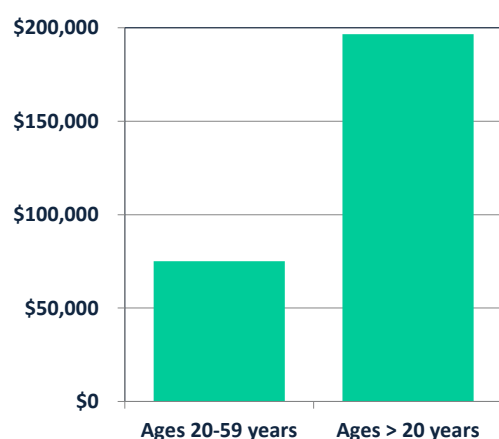
Benefits: Evidence Type†

Outcome	Study design (numbers)	Findings	Evidence type	Overall evidence type
Hepatitis B Infection Events	Randomized Clinical Trials(6)	Decreased risk among those vaccinated	2	2
Seroprotection	Observational Studies (5)	Similar seroprotection among those with and without diabetes	4	

Potential Harms

- 2011 Institute of Medicine Report
 - Evidence supports a causal relationship between hepatitis B vaccine and anaphylaxis in yeast-sensitive individuals
- Anaphylaxis following hepatitis B vaccination
 - Estimate 1.1 per million doses administered (95% CI, 0.1-3.9)

Cost per Quality-Adjusted Life Year Saved



New ACIP Recommendation

- Hepatitis B vaccination should be administered to unvaccinated adults with diabetes mellitus who are aged 19 through 59 years (recommendation category A, evidence type 2)
- Hepatitis B vaccination may be administered at the discretion of the treating clinician to unvaccinated adults with diabetes mellitus who are aged ≥60 years (recommendation category B, evidence type 2)
- Decisions to vaccinate adults aged ≥60 years with diabetes should incorporate:
 - Likelihood of acquiring HBV infection, including risk posed by need for assisted blood-glucose monitoring in long-term care facilities
 - Likelihood of experiencing chronic sequelae if infected
 - Declining response to vaccine associated with frailty

References

Thompson. *J Diabetes Sci Technol* 2009;3:283-88; Klonoff. *J Diabetes Sci Technol* 2010;4:1027-31; Bohlke. *Pediatrics* 2003;112:815-20; DiMiceli. *Vaccine* 2006;24:703-7; IOM 2011. Adverse Effects of Vaccines: Evidence and Causality; Hoerger et al. Research Triangle Institute, Int.

†Evidence type 1: randomized controlled trials, or overwhelming evidence from observational studies. Evidence type 2: randomized controlled trials with important limitations, or exceptionally strong evidence from observational studies. Evidence type 3: observational studies, or randomized controlled trials with notable limitations. Evidence type 4: clinical experience and observations, observational studies with important limitations, or randomized controlled trials with several major limitations. Recommendation category A: a recommendation that applies to all persons in an age or risk-based group. Recommendation category B: a recommendation for individual clinical decision making.

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Division of Viral Hepatitis



E-mail: cdcinfo@cdc.gov | Web: www.cdc.gov

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