Hepatitis B Vaccination of Adults with Diabetes Mellitus

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Advisory Committee on Immunization Practices (ACIP) Recommendations
ACIP Recommendation for Hepatitis B Vaccination of Adults with DM

Use of Hepatitis B Vaccination for Adults with Diabetes Mellitus:
Recommendations of the Advisory Committee on Immunization Practices (ACIP)

Hepatitis B virus (HBV) causes acute and chronic infections of the liver leading to substantial morbidity and mortality. In the United States since 1996, a total of 29 outbreaks of HBV infection in one or multiple long-term-care (LTC) facilities, including nursing homes and assisted-living facilities, were reported to CDC. Of these, 25 involved adults with diabetes receiving assisted blood glucose monitoring (3, CDC, unpublished data, 2011). These outbreaks prompted the Hepatitis Vaccine Work Group of the Advisory Committee on Immunization Practices (ACIP) to evaluate the risk for HBV infection among all adults with diagnosed diabetes. The Work Group reviewed 117 published articles on vaccines and the effectiveness of implementing infection prevention and control measures. The strength of scientific evidence regarding protection was evaluated using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) methodology (4) and safety, tolerability, and cost-effectiveness were reviewed. Articles were reviewed using the GRADE system, based on the Work Group findings on October 25, 2011. ACIP recommended that all previously unvaccinated adults aged 19 through 63 years with diabetes mellitus (type 1 and type 2) be vaccinated against hepatitis B as soon as possible after a diagnosis of diabetes is made (recommendation category A). Data on the risk for hepatitis B among adults aged ≥60 years are less robust. Therefore, ACIP recommended that all previously unvaccinated adults aged ≥60 years with diabetes may be vaccinated at the discretion of the treating clinician after assessing the risk (category B). This recommendation is based on the ACIP’s evidence-based recommendations for hepatitis A vaccine (5) and the 2010 ACIP guidelines for hepatitis B vaccine (6). Table 2 summarizes these recommendations and provides the rationale used by ACIP to inform their decision making.

Risk for HBV Infection

An estimate of the risk for HBV infection for adults with diabetes living in LTC facilities was not available. Existing studies suggest that it might be substantial. The population

Recommendations

- Hepatitis B vaccination should be administered to unvaccinated adults with diabetes mellitus who are aged 19 through 59 years (recommendation category A)

- 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)

Category A: Applies to all persons in an age- or risk-based group
Category B: For individual clinical decision making

MMWR 2011 Dec 23;60(50):1709-11.
Hepatitis B Vaccination for Adults with Diabetes

- Vaccination should be completed as soon as feasible after diabetes is diagnosed.
- No serologic testing or additional hepatitis B vaccination is recommended for adults who received a complete series of hepatitis B vaccinations at any time in the past.
- Available data do not confirm an advantage to any specific vaccine, dosage, or approved schedule for adults with diabetes.

MMWR 2011 Dec 23;60(50):1709-11.
Vaccinating Adults with Diabetes Aged ≥60 Years

- **Decisions should incorporate:**
  - Likelihood of acquiring HBV infection, including the risk posed by assisted blood-glucose monitoring in long-term care facilities
  - Likelihood of experiencing chronic sequelae if infected with HBV
  - The declining immunologic responses to vaccines that are associated with frailty

MMWR 2011 Dec 23;60(50):1709-11.
Considerations for Recommendation of Hepatitis B Vaccine for Adults with Diabetes
Diabetes Mellitus (DM) and Hepatitis B Virus (HBV) Infection

- Increased risk of HBV infection among persons with DM
  - Persons with DM may acquire HBV infection from lapses in infection control during blood glucose monitoring

Transmission of HBV during Healthcare Delivery

1. High titer of HBV: Present in absence of visible blood

2. Stable on environmental surfaces for ≥7 days

3. Transmission via contaminated equipment*, surfaces, or medication vials

*Lancets, glucose meters, insulin pens
Blood Glucose Monitoring

- **Essential component of diabetes management**
  - ~86% check blood glucose at least monthly*, including persons treated with insulin, oral medications, and nutritional therapy

- **Procedure**
  - Test strip inserted into meter
  - Blood drawn with fingerstick device
  - Blood applied to test strip

Outbreaks of Hepatitis B Virus (HBV) Infection associated with Blood Glucose Monitoring — United States, 1990-2010

- Hospital (2)
- Nursing Home (8)
- Assisted Living Facility (16)

## Mis-use of Diabetes Equipment: Recent Patient Notifications

<table>
<thead>
<tr>
<th>Year, setting</th>
<th>Equipment misused</th>
<th>Length of misuse</th>
<th>Persons at risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008, Hospital</td>
<td>Insulin pen</td>
<td>7 months</td>
<td>908</td>
</tr>
<tr>
<td>2009, Hospital</td>
<td>Insulin pen</td>
<td>7 months</td>
<td>2114</td>
</tr>
<tr>
<td>2009, Community Health Center</td>
<td>Multi-lancet finger stick device</td>
<td>6 months</td>
<td>283</td>
</tr>
<tr>
<td>2010, Health fair</td>
<td>Multi-lancet finger stick device</td>
<td>1 day</td>
<td>64</td>
</tr>
<tr>
<td>2011, HMO, certified diabetes educator</td>
<td>Multi-lancet finger stick device, insulin pen</td>
<td>5+ years</td>
<td>2345</td>
</tr>
</tbody>
</table>

Settings Where Persons Receive Assistance with Blood Glucose Monitoring

- Hospitals
- Nursing homes
- Assisted living facilities
- Prisons
- Home health care
- Medical practitioners’ offices or clinics
- Diabetes research laboratories
- Health fairs
- Schools
- Children’s camps
- Shelters


- Nationally representative survey of non-institutionalized adults; tested for antibody to hepatitis B core antigen (anti-HBc)

- Unadjusted prevalence ratios of anti-HBc among adults with diabetes (vs. without diabetes)
  - Ages 18-59 years: 1.7 (1.3-2.2)
  - Ages ≥60 years: 1.3 (1.0-1.6)

Acute Hepatitis B: Emerging Infections Program (EIP), 2009-2010

- 865 cases from 8 EIP surveillance sites
- To determine the odds of acute hepatitis B among adults with diabetes, controlling for potential confounders
- Adjusted OR (Models controlled for sex, age, and race/ethnicity and excluded persons with other HBV risk behaviors):
  - Ages 23-59 years: 2.1 (1.6-2.8)
  - Ages ≥60 years: 1.5 (0.9-2.5)

Distribution (%) of Age at Diagnosis of Diabetes, 2011

CDC. Diabetes Data and Trends: National Diabetes Surveillance System
www.cdc.gov/diabetes/statistics. Data from the National Health Interview Survey.
Burden of HBV Prevented with 10% Vaccine Uptake (Lifetime Perspective): Modeling Analysis

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Infected</th>
<th>Hospitalizations</th>
<th>Chronic cases</th>
<th>Cirrhosis</th>
<th>HCC</th>
<th>Transplants</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-59</td>
<td>4,271</td>
<td>467</td>
<td>256</td>
<td>202</td>
<td>33</td>
<td>13</td>
<td>130</td>
</tr>
<tr>
<td>≥60</td>
<td>723</td>
<td>79</td>
<td>43</td>
<td>22</td>
<td>3</td>
<td>1</td>
<td>11</td>
</tr>
</tbody>
</table>

HCC=hepatocellular carcinoma

Number of persons with diabetes needed to vaccinate to prevent one HBV infection (modeling analysis)

- Age 20-59 years: 124
- Age ≥60 years: 1,071

Hepatitis B Vaccine Seroprotection (anti-HBs ≥10 mIU/mL) among Persons with Diabetes

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Total N</th>
<th>Mean age*</th>
<th>Dose (mcg)</th>
<th>Route</th>
<th>Schedule (mos)</th>
<th>Diabetes (%, 95% CI)</th>
<th>Non-Diabetes (%, 95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arslanoglu, 2002</td>
<td>150</td>
<td>11</td>
<td>10</td>
<td>IM</td>
<td>0,1,6</td>
<td>94 (88-98)</td>
<td>98 (88-100)</td>
</tr>
<tr>
<td>Bouter, 1992</td>
<td>64</td>
<td>34</td>
<td>20</td>
<td>IM</td>
<td>0,1,6</td>
<td>75 (56-88)</td>
<td>97 (82-100)</td>
</tr>
<tr>
<td>Douvin, 1997</td>
<td>71</td>
<td>52/46</td>
<td>20</td>
<td>IM</td>
<td>0,1,2,12‡</td>
<td>92 (82-97)</td>
<td>--</td>
</tr>
<tr>
<td>Li Volti, 1998</td>
<td>42</td>
<td>9</td>
<td>3-20</td>
<td>IM, ID</td>
<td>0,1,6§</td>
<td>89 (64-98)</td>
<td>100 (83-100)</td>
</tr>
<tr>
<td>Marseglia, 1996</td>
<td>239</td>
<td>17</td>
<td>10¶</td>
<td>IM</td>
<td>0,1,6</td>
<td>95 (86-99)</td>
<td>98 (95-100)</td>
</tr>
</tbody>
</table>

*Among subjects with diabetes, ‡30 subjects received a booster dose at month 4, §2, 4, 6, 8 weeks for ID route; ¶One 4.5 year-old subject received 5 mcg
Hepatitis B Vaccine Coverage (≥3 doses) among Adults Aged ≥19 Years, National Health Interview Survey (NHIS) – U.S., 2014

Conclusions

- Adults with diabetes at elevated risk for HBV infection
  - Infection control lapses with blood glucose monitoring

- Hepatitis B vaccination recommended for adults with diabetes in United States since 2011
  - Aged 19-59 years: All persons
  - Aged 60 years and older: Based on risk

- Vaccine coverage among adults with diabetes remains low
Acknowledgements

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Questions?

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