ACIP Recommendations for HepB-CpG

Quarterly Call
National Adult Immunization Coordinators’ Partnership
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David Kim, MD
Immunization Services Division
National Center for Immunization and Respiratory Diseases
Updates – Hepatitis B Vaccination

- Heplisav-B (Dynavax) is single-antigen hepatitis B vaccine, given as 2-doses series (0 and 1 month) as I.M. injection

- FDA-approved November 2017 for adults >18yo

- ACIP recommendations published April 2018
  - Not in 2018 adult schedule

- Contains yeast-derived recombinant HBsAg with Cytosine-phosphate-Guanine (CpG) adjuvant

- Revised hepatitis B vaccine nomenclature
  - HepB = Hepatitis B vaccine
  - HepB-CpG = Cytosine-phosphate-Guanine-adjuvanted HepB
  - HepB-alum = aluminum-adjuvanted HepB

- Current Hepatitis B VIS may be used

HepB-CpG – Seroprotection and Safety\(^1-3\)

- **Immunogenicity**
  - 90%–100% (2 doses) vs. 70%–90% in comparison group (3 doses Engerix-B)
  - Diabetes Type II: 90% (2 doses) vs. 65% (3 doses Engerix-B)
  - Chronic kidney disease: 90% (3 doses) vs. 81% (4 double doses Engerix-B)

- **Safety and reactogenicity**
  - Mild and serious adverse events similar
    - Mild: 46% vs. 46%
    - Serious: 5% vs. 6%
  - Cardiovascular events not significantly different
    - 0.3% vs. 0.1%
  - Potentially immune-mediated adverse events similar (e.g., granulomatosis with polyangiitis, Grave’s disease)
    - 0.1%–0.2% vs. 0%–0.7%

**Recommendations – Hepatitis B Vaccination**

- Recommended HepB-CpG use – 2 doses 1 month apart for persons aged \( \geq 18 \text{y} \) (not in 2018 adult immunization schedule)
- No preferential recommendation for use of HepB-CpG over HepB-alum
- HepB-CpG may be used in 3-dose HepB-alum series
  - 3 doses of HepB are needed unless 2 doses of HepB-CpG is administered 1 month apart

“The 2-dose HepB vaccine series only applies when both doses in the series consist of HepB-CpG. Series consisting of a combination of 1 dose of HepB-CpG and a vaccine from a different manufacturer should consist of 3 total vaccine doses and should adhere to the 3-dose schedule minimum intervals of 4 weeks between dose 1 and 2, 8 weeks between dose 2 and 3, and 16 weeks between dose 1 and 3. Doses administered at less than the minimum interval should be repeated. However, a series containing 2 doses of HepB-CpG administered at least 4 weeks apart is valid, even if the patient received a single earlier dose from another manufacturer.”

1. MMWR 67(15);455–458