



ACIP Recommendations for HepB-CpG

Quarterly Call

National Adult Immunization Coordinators' Partnership

July 10, 2018

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 ¹
- 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

1. HEPLISAV-B™ [Hepatitis B Vaccine (Recombinant), Adjuvanted] package insert www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM584762.pdf

HepB-CpG – Seroprotection and Safety¹⁻³

■ Immunogenicity

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

1. Jackson S, Lentino J, Kopp J, et al. Immunogenicity of a two-dose investigational hepatitis B vaccine, HBsAg-1018, using a toll-like receptor 9 agonist adjuvant compared with a licensed hepatitis B vaccine in adults. *Vaccine* 2017; 36:668-74
2. Janssen R, Bennett S, Namini H, et al. Immunogenicity and Safety of Two Doses of Investigational Heplisav Compared to Three Doses of Licensed Hepatitis B Vaccine (Enderix-B) in Two Phase 3 Trials. *Journal of Hepatology* 2013; 58(Suppl 1):S574
3. HEPLISAV-B™ [Hepatitis B Vaccine (Recombinant), Adjuvanted] package insert www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM584762.pdf

Recommendations – Hepatitis B Vaccination¹

- Recommended HepB-CpG use – 2 doses 1 month apart for persons aged ≥18y (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.”