Heplisav-B versus Engerix-B in Adults 18-70 Years of Age

HBV-23 Trial

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HBV-23 Trial: Study Design

- **Background**
  - Phase 3 observer-blinded active-controlled randomized trial to assess the immunogenicity of Heplisav-B (HBsAg-1018) vaccine versus Engerix-B vaccine in adults 18-70 years of age, with or without diabetes.
- **Participants**
  - n = 8,374 persons, including 961 with type 2 diabetes mellitus
  - Ages: 18-70 years
  - HBV vaccine naïve
  - Exclusions: HBV, HIV, pregnancy or lactation, chronic steroid use, autoimmune condition
- **Study End Point**
  - Seroprotection = anti-HBs antibody level ≥10 mIU/mL

*Any positive for HBsAg, anti-HBs, or anti-HB core

Source: Jackson S, et al. Vaccine. 2018;36:668-674.

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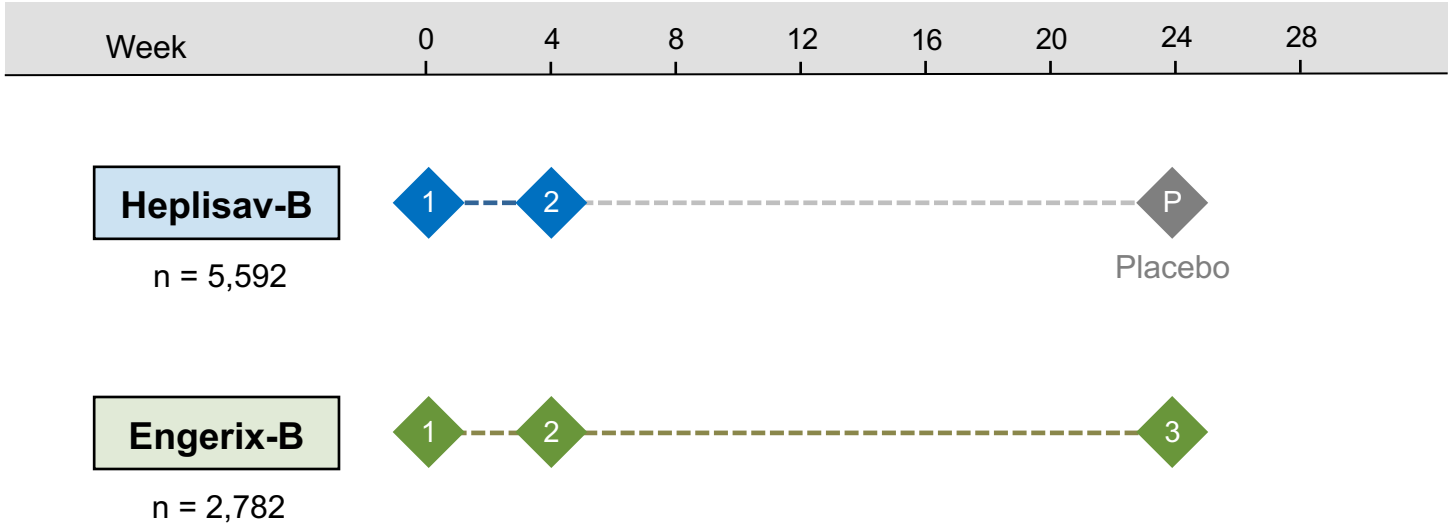

Vaccine Dosing

Heplisav-B: 0.5 mL dose of 3 mg 1018 adjuvant with 20 mcg recombinant HBsAg at week 0 and 4, followed by administration of saline placebo at week 24

Engerix-B: 1 mL dose of 20 mcg recombinant HBsAg with aluminum adjuvant at week 0, 4 and 24

Source: Jackson S, et al. Vaccine. 2018:36:668-74.

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HBV-23 Trial: Baseline Characteristics

Baseline Characteristic	Heplisav-B (n = 5,592)	Engerix-B (n = 2,782)
Age, mean (SD), years	50.4 (11.7)	50.4 (11.7)
Male, no. (%)	2845 (51)	1391 (50)
Race, no. (%)		
White	3972 (71)	2007 (72)
Black	1462 (26)	697 (25)
Asian	57 (1)	38 (1.4)
American Indian/Alaskan Native	60 (1)	24 (1)
Other	41 (1)	16 (0.6)
Body mass index (BMI), mean (SD), kg/m^2	31 (7.5)	31 (7.6)
BMI ≧30 kg/m^2, n (%)	2728 (49)	1286 (46)
Smoker, n (%)	1844 (33)	909 (33)
Diabetes type 2, n (%)	763 (13.6)	381 (13.7)

Source: Jackson S, et al. Vaccine. 2018:36:668-74.

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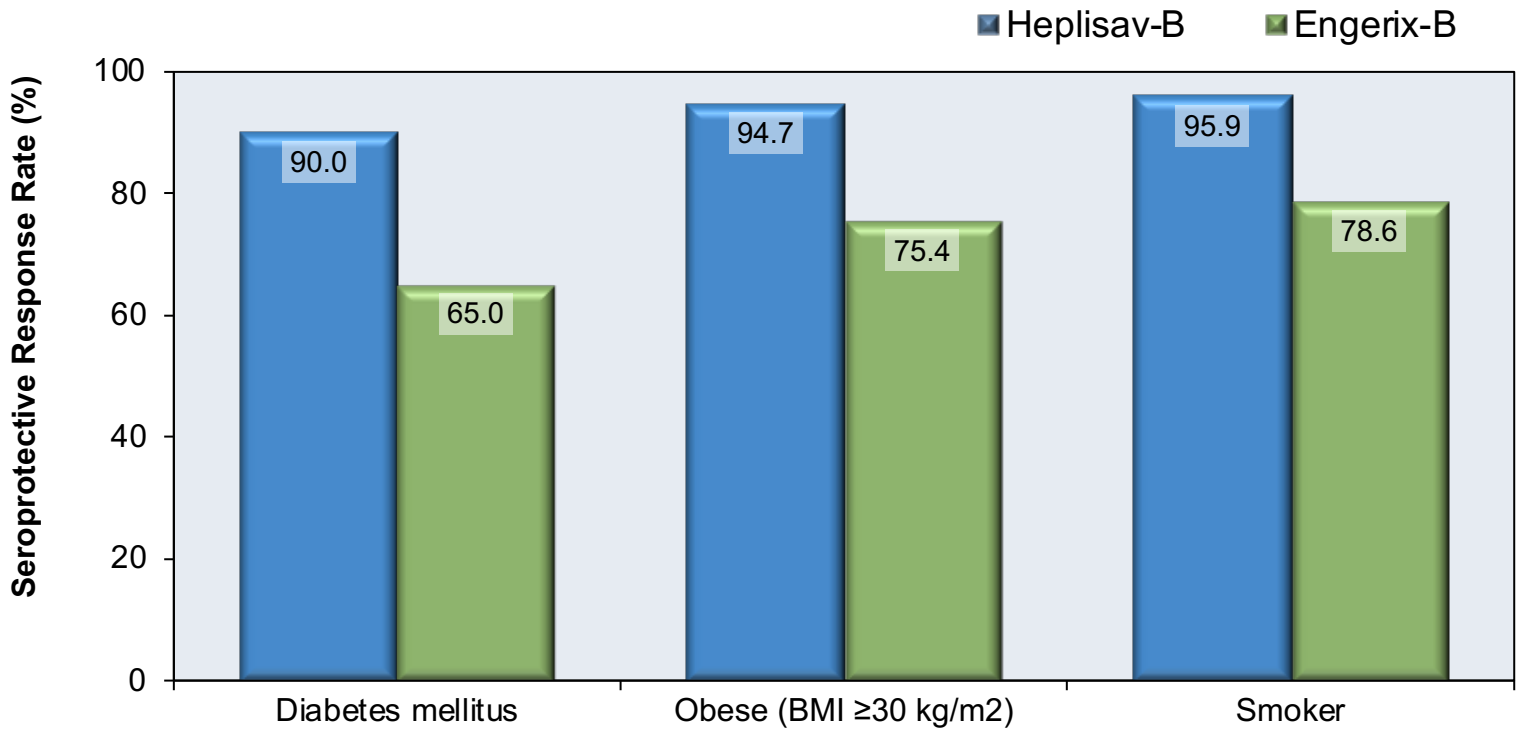
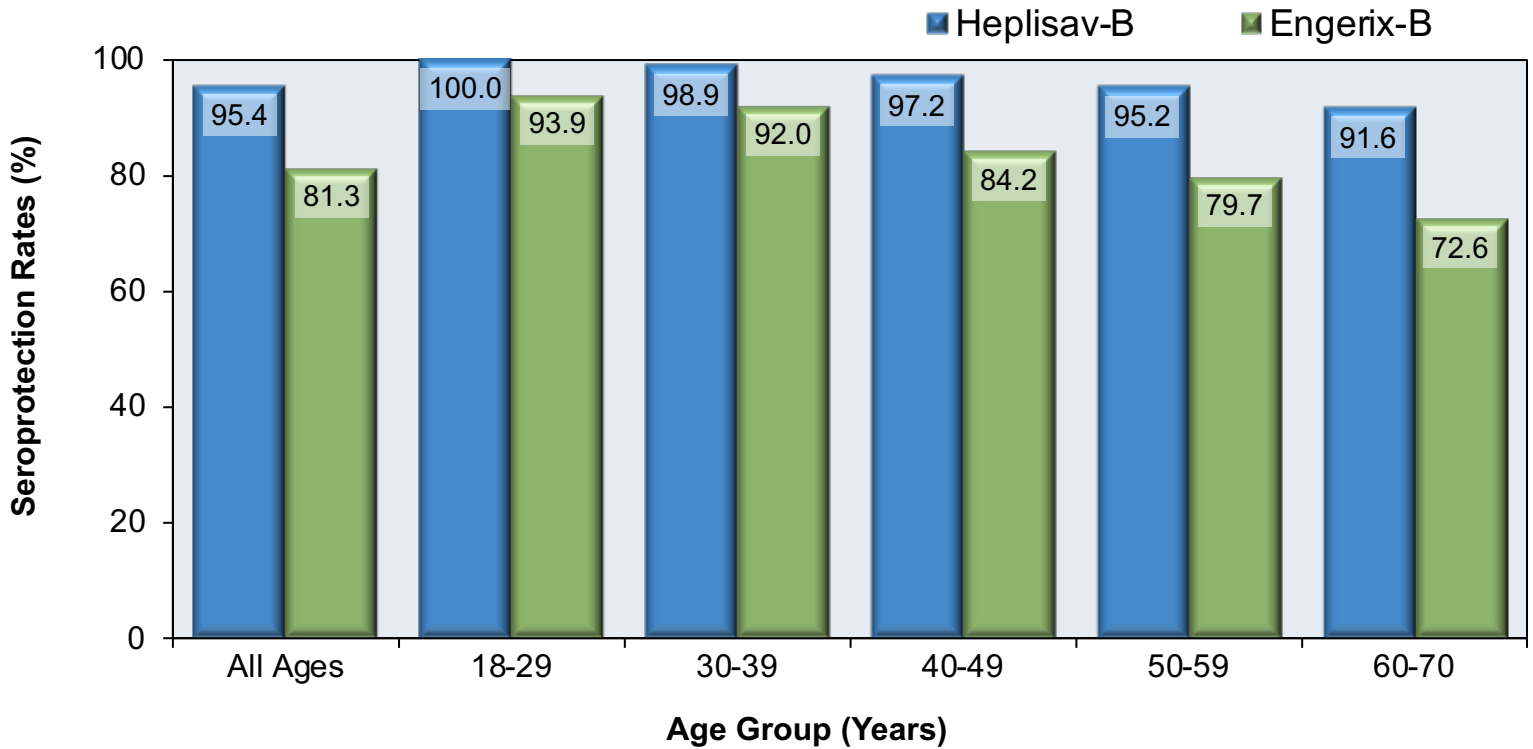
HBV-23 Trial: Results, by Key Subgroups



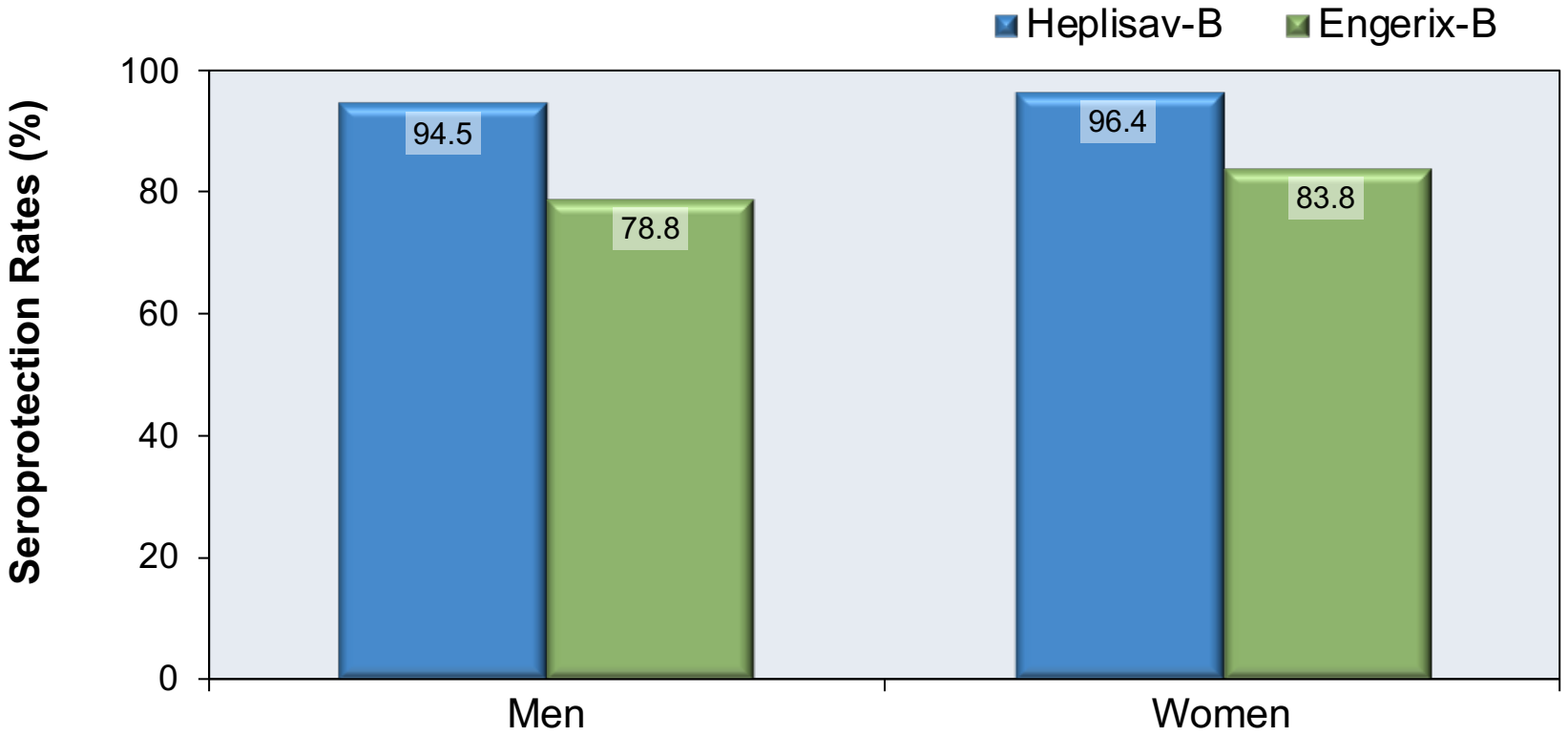
Source: Jackson S, et al. Vaccine. 2018:36:668-74.

Heplisav-B versus Engerix-B in Adults 18-70 Years of Age
HBV-23 Trial: Results, by Age Group



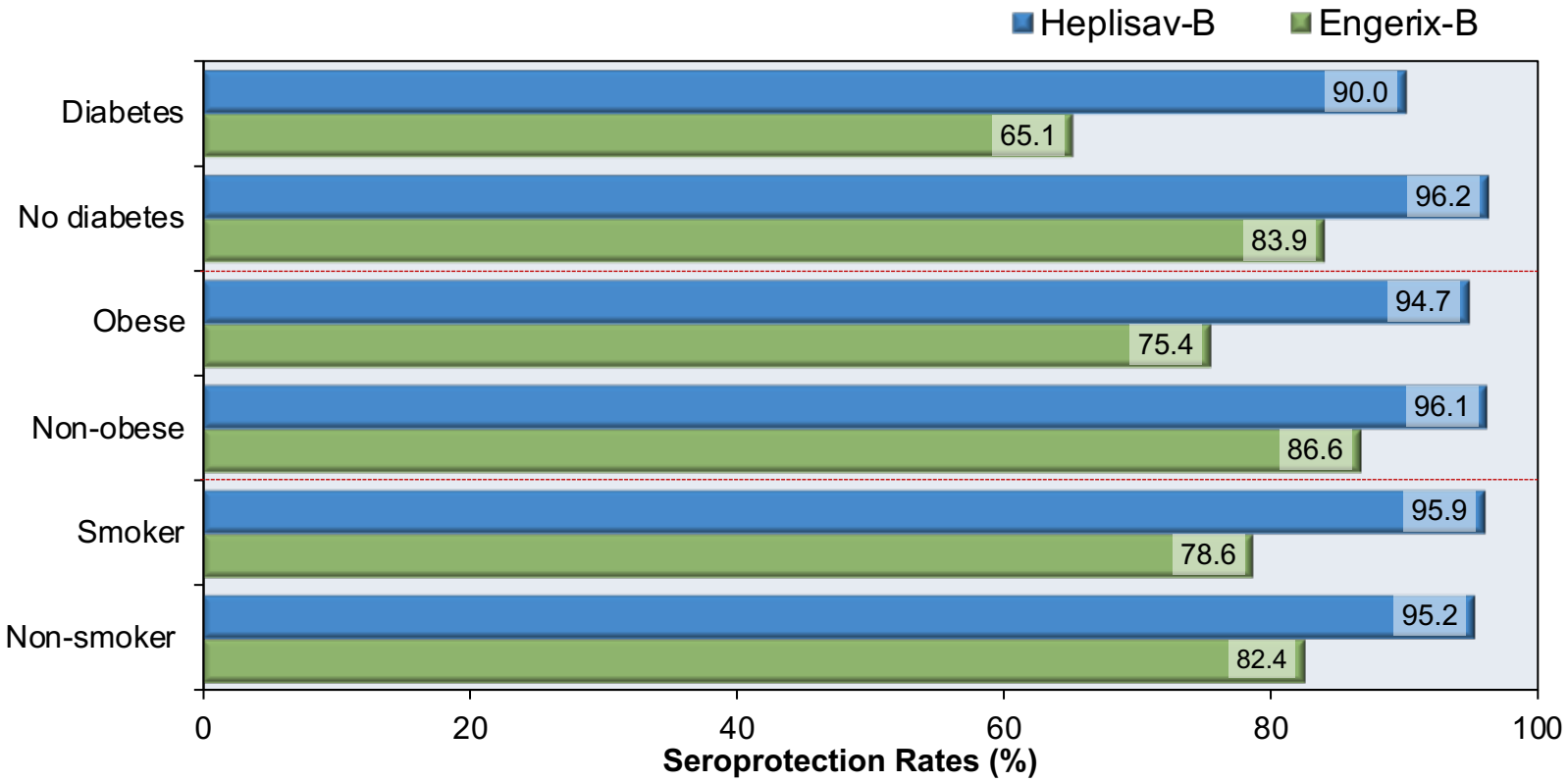
Source: Jackson S, et al. Vaccine. 2018:36:668-74.

Heplisav-B versus Engerix-B in Adults 18-70 Years of Age
HBV-23 Trial: Results, by Gender



Source: Jackson S, et al. Vaccine. 2018:36:668-74.

Heplisav-B versus Engerix-B in Adults 18-70 Years of Age
HBV-23 Trial: Results, by Comorbidities



Source: Jackson S, et al. Vaccine. 2018:36:668-74.

Heplisav-B versus Engerix-B in Adults 18-70 Years of Age
HBV-23 Trial: Conclusions

Conclusions: “Two doses of HBsAg-1018, administered over 4 weeks, induced significantly higher seroprotection rates than three doses of HBsAg-Eng, given over 24 weeks, in adults with factors known to reduce the immune response to hepatitis B vaccines as well as in those without those factors. With fewer doses in a shorter time, and greater immunogenicity, HBsAg-1018 has the potential to significantly improve protection against hepatitis B in adults at risk for hepatitis B infection.”

Source: Jackson S, et al. Vaccine. 2018:36:668-74.

This slide deck is from the University of Washington's *Hepatitis B Online* and *Hepatitis C Online* projects.

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www.hepatitisB.uw.edu

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