Hepatitis B Vaccines

PAULINA DEMING, PHARMD, PHC
ASSOCIATE PROFESSOR OF PHARMACY-COLLEGE OF PHARMACY
ASSOCIATE DIRECTOR- VIRAL HEPATITIS PROGRAMS, PROJECT ECHO
UNIVERSITY OF NEW MEXICO HEALTH SCIENCES CENTER

Conflict of Interest Disclosure Statement

Speaker has no relevant conflicts of interest to disclose.

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Some slides are courtesy of vaccine manufacturer

Learning Objectives

1. Review hepatitis B serology test interpretation
2. Identify screening recommendations for HBV
3. Recognize vaccines available for hepatitis B virus (HBV) infections
4. Differentiate between the available HBV vaccines
5. Discuss vaccine response and need for re-vaccination

Who Should be Screened for Hepatitis B Virus?

All adults 18 years and older should be tested for HBV at least once during their lifetime using the triple panel:

- Hepatitis B surface antigen (HBsAg)
- Antibody to hepatitis B surface antigen (anti-HBs)
- Total antibody to hepatitis B core antigen (total anti-HBc)

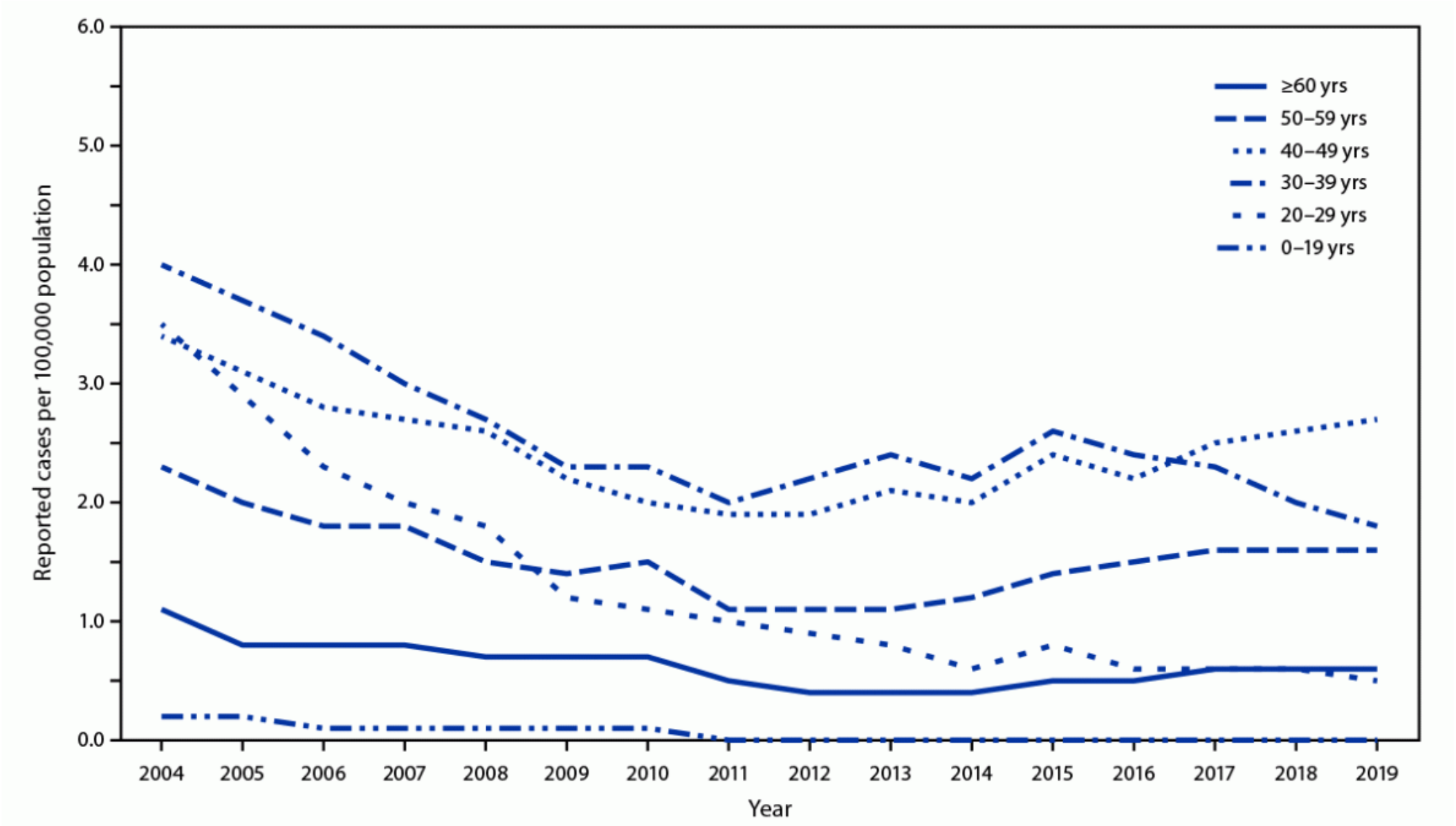
Screen all pregnant people at each pregnancy for HBsAg

HBsAg	Anti-HBs	Anti-HBc	Interpretation
+	-	+ IgM	Acute infection
+	+/-	+IgG	Chronic Infection
-	+	-	Immune from Prior Vaccination
-	+	+	Exposure with immune control; low risk of reactivation[1]
-	-	+	Exposure with minimal or no immune control; higher risk of reactivation[1,2]

[1]No need for HBV vaccination

[2] If ALT elevated or immune –suppressed consider evaluation for occult HBV with HBV DNA

FIGURE. Rates of reported acute hepatitis B virus infection, by age group — United States, 2004–2019



Source: https://www.cdc.gov/hepatitis/statistics/2019surveillance/Figure2.4.htm

ACIP Recommendations for HBV Vaccine

All infants

All persons aged <19 years

Any adults age 19-59 should complete a 2, 3, or 4 dose vaccine series

Anyone age 60 years or older* and at risk for HBV infection

- Chronic liver disease
- HIV infection
- Sexual exposure
- Current or recent injection drug use
- Percutaneous or mucosal risk for exposure to blood
- Incarcerated persons
- Travel in countries with high or intermediate endemic HBV

***ANYONE age 60 or older who wants vaccine**

MMWR Feb. 18, 2022/ 71(7);229-233

Vaccine Update

PreHevBrio withdrawn from market (effective November 29, 2024)

Voluntary recall due to bankruptcy of company and termination of operations

- NOT safety or effectiveness concerns with vaccine
- VBI vaccines requests notification of vaccine disposition to prehevbrio@vbivaccines.com

	Engerix-B	Recombivax	HeplisavB
Viral antigen	sAg	sAg	sAg
Derivation	Yeast	Yeast	Yeast
Adjuvant	Aluminum hydroxide	Aluminum hydroxide	Cp-g 1018
Dose	20 micrograms (double dose recommended for PWH)	10 or 40 micrograms (HD) (double dose recommended for PWH)	20 micrograms
Number of Doses	3	3	2
Schedule	0,1, 6 mo	0,1, 6 mo	0, 1 mo

Vaccine Response

Immunocompetent children and adults who have vaccine-induced anti-HBs levels of ≥10 mIU/mL 1-2 months after receiving a complete HepB vaccine series are considered vaccine responders

- Vaccine response is age related
  - 16% if before age 1
  - 74% if vaccinated at age 1 or older

Document anti-HBs >10mIU/mL 4 weeks after last dose of vaccine in persons with HIV (PWH)

CDC. Hepatitis B Questions and Answers for Health Professionals. Available at: https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm

How long does HBV vaccine immunity last?

Immunity remains for at least 30 years among healthy people who received vaccine at less than 6 months of age

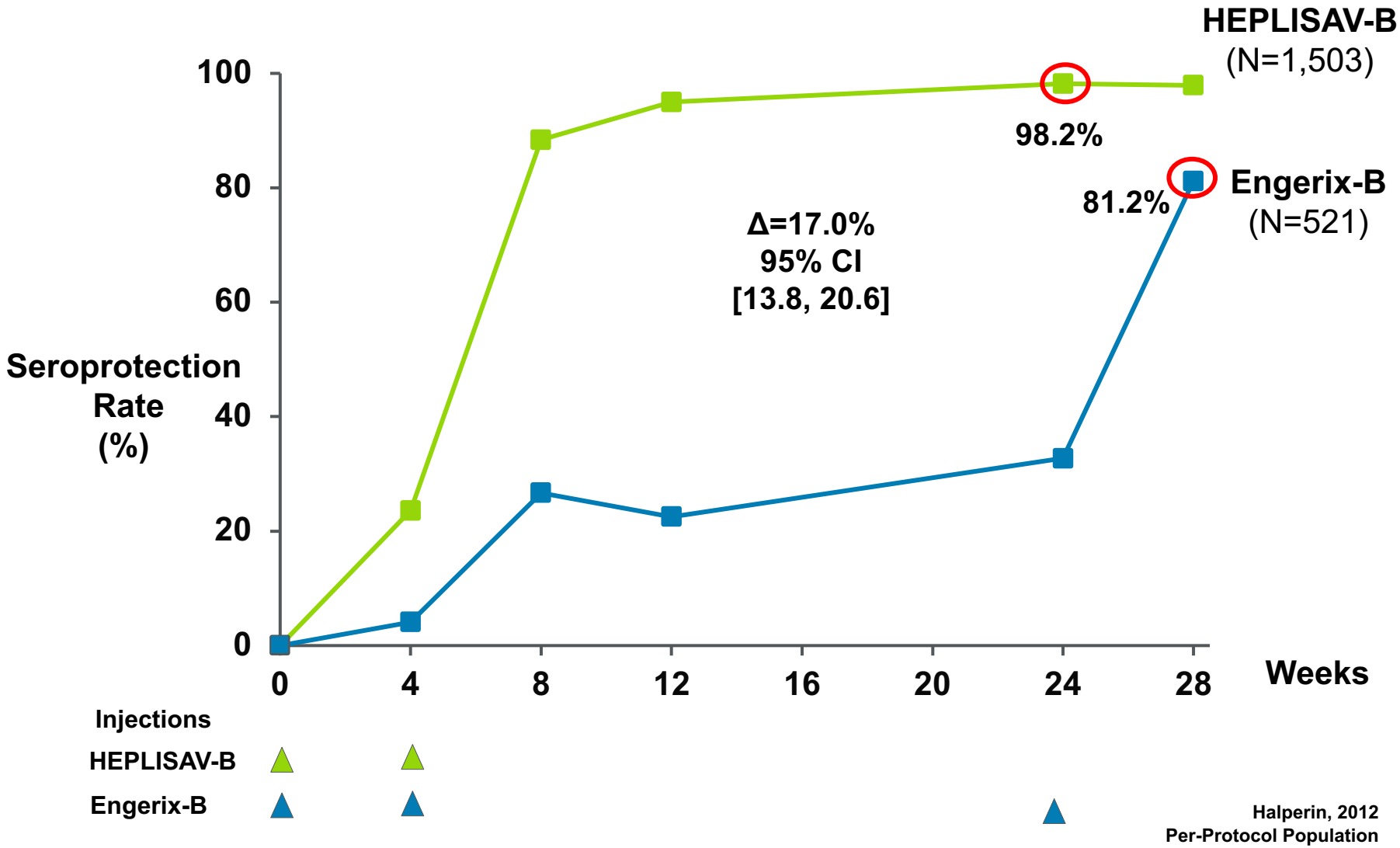
- 88% of patients receiving challenge dose 30 years after HBV vaccination show persistent antibody response (≥10 mIU/mL)

Cellular immunity persists even when antibody titers drop below detectable levels

- No need to routinely test for anti-HBs in immunocompetent patients

CDC. Hepatitis B Questions and Answers for Health Professionals. Available at: https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm

HBV-10: HEPLISAV-B Induced Higher Peak Seroprotection Rates



Halperin, 2012
Per-Protocol Population

HBV-23: Higher Seroprotection Rates for HEPLISAV-B in Pre-specified Populations

	HEPLISAV-B N	Engerix-B N	Peak SPR (%)	
			HEPLISAV-B	Engerix-B
Total population	4,376	2,289	95.4%	81.3%
Non-diabetes	3,762	1,968	96.2%	83.9%
Diabetes	640	321	90.0%	65.1%
18 – 29 years	174	99	100.0%	93.9%
30 – 39 years	632	326	98.9%	92.0%
40 – 49 years	974	518	97.2%	84.2%
50 – 59 years	1,439	758	95.2%	79.7%
60 – 70 years	1,157	588	91.6%	72.6%
Men	2,203	1,150	94.5%	78.8%
Women	2,173	1,139	96.4%	83.8%
Obese	2,165	1,076	94.7%	75.4%
Non-obese	2,208	1,212	96.1%	86.6%
Smoker	1,371	711	95.9%	78.6%
Non-smoker	3,005	1,578	95.2%	82.4%

Jackson, 2018
Per-Protocol Population

Vaccine Interchangeability

Best: complete vaccine series using same manufacturer

Complete vaccine series with same antigen vaccine:

3 total doses adhering to 3 dose schedule with minimum

- 4 week interval between dose 1 and 2
- 8 weeks between dose 2 and 3
- and 16 weeks between dose 1 and 3

After first dose of 3-dose vaccine, ok to then use 2 dose vaccine to complete vaccination series as long as doses administered at least 4 weeks apart

No Data: Completing a vaccine series using various antigen vaccines

Schillie S et al. MMWR. April 20, 2018. 67 (15);455-458.

What About Interruptions in Dosing of HBV Vaccines?

The vaccine series does NOT need to be restarted

If interruption after first dose, second dose should be given as soon as possible

The second and third dose should be separated by ***at least*** 8 weeks

If third dose is delayed, administer as soon as possible

CDC. Hepatitis B Questions and Answers for Health Professionals. Available at: https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm

Who Needs Post-Vaccine Serology Testing?

Infants born to people who test positive for HBsAg

Health care workers and public safety workers who are at high risk for continued percutaneous or mucosal exposure to blood or body fluids

Patients on hemodialysis, people with HIV (PWH), people who are immunocompromised (hematopoietic stem cell transplant recipients, patients receiving chemotherapy)

Sex partners of people with chronic HBV

CDC. Hepatitis B Questions and Answers for Health Professionals. Available at: https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm

Is Hepatitis B Vaccine Booster Dosing Recommended?

Not for people with normal immune status who have been vaccinated

Patients on hemodialysis, if annual testing indicates anti-HBs <10 mIU/mL, give booster dose

For patients with HIV, hematopoietic stem-cell transplant recipients, or people receiving chemotherapy, *need for booster dosing not determined*

- Annual anti-HBs testing and booster doses should be considered in those with on-going risk for exposure

CDC. Hepatitis B Questions and Answers for Health Professionals. Available at: https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm

Key Points

2022 ACIP recommendations for HBV vaccine for all persons 19-59

Heplisav-B offers improved seroprotective rates as compared to historical vaccines

Post vaccine serological testing recommended in specific patient populations (patients on hemodialysis, PWH, immunocompromised)