

Overview

- **Welcome and Introduction – Dr. Noele Nelson**
- **Presentation – Dr. Erin Conners**
 - Hepatitis B in the United States
 - Methods of guideline development
 - Proposed recommendation language
 - Process for providing feedback
- **Question and Answer period – Drs. Laura Cooley and Noele Nelson**
- **Closing remarks – Dr. Carolyn Wester**

Introduction

- **The purpose of this webinar is to:**
 - present the draft of the updated hepatitis B screening recommendations
 - describe how to provide feedback via the Federal Register notice (FRN)
- **These slides will be posted on:**
<https://www.cdc.gov/hepatitis/policy/ISlreview/index.htm>

Introduction

- **All participants will be muted for the duration of the webinar.**
- **Please add any questions about the FRN process or clarification about the guidelines in the Q&A box**
 - All public comments must be submitted through the FRN; CDC highly encourages review and feedback
 - Questions regarding the FRN process or clarification of presentation content will be answered at the end of the presentation



Overview of Draft CDC Recommendations for Hepatitis B Screening and Testing

Erin Conners, PhD, MPH

**Epidemiologist, Clinical Interventions Team, Division of
Viral Hepatitis**

April 20, 2022

Disclaimer

This presentation is distributed solely for the purpose of predissemination review. These materials have not been formally disseminated by the Centers for Disease Control and Prevention. Draft materials shared for review do not represent and should not be construed to represent any agency determination or policy.

Acknowledgements

Guideline workgroup and steering committee

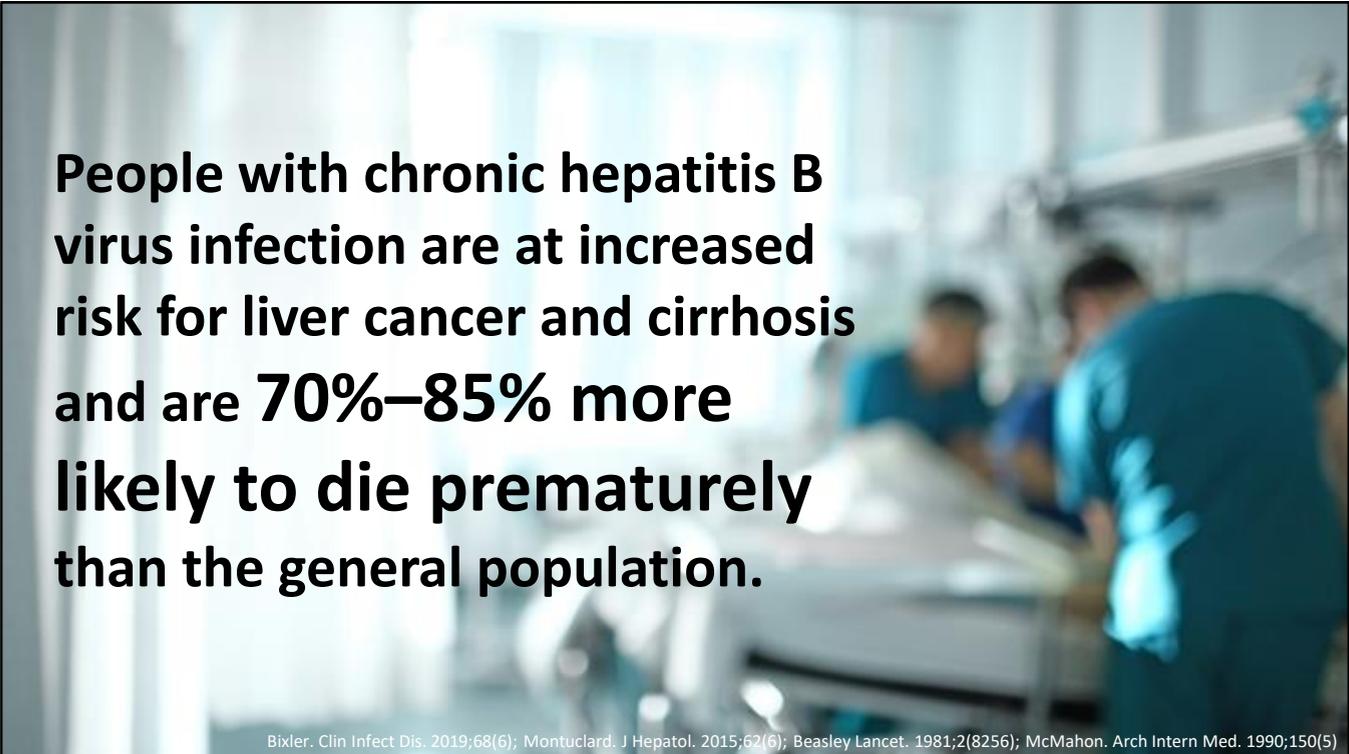
- Noele Nelson
- Jessica Brown
- Liesl Hagan
- Aaron Harris
- Megan Hofmeister
- Lakshmi Panagiotakopoulos
- Karina Rapposelli
- Amy Sandul
- Philip Spradling
- Carolyn Wester

Other CDC Consultation and Support

- NCHHSTP Office of the Director
- Guidelines and Recommendations Activity
- Strategic Business Initiatives Unit
- MMWR Serials Team

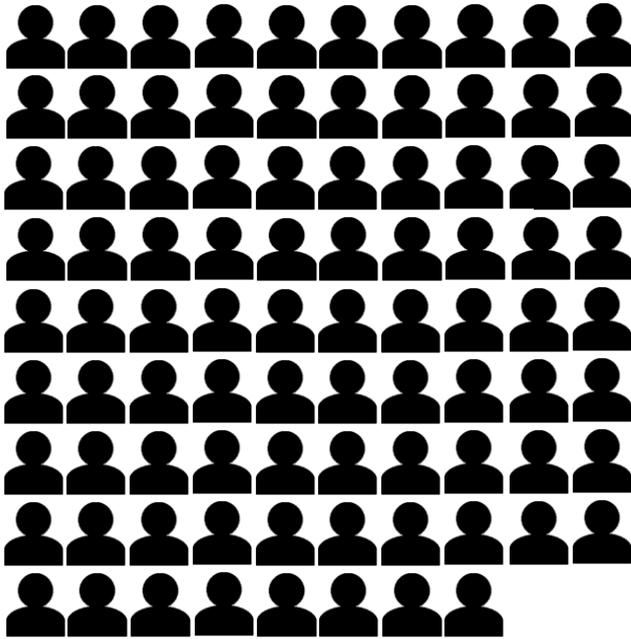
Prevention Policy Modeling Lab

- Mehlika Toy
- David Hutton
- Joshua Salomon
- Samuel So

A blurred background image of a hospital room. In the foreground, a person in blue scrubs is seen from behind, looking towards a patient in a hospital bed. Other medical staff are visible in the background, also in blue scrubs. The scene is brightly lit, likely from large windows in the background.

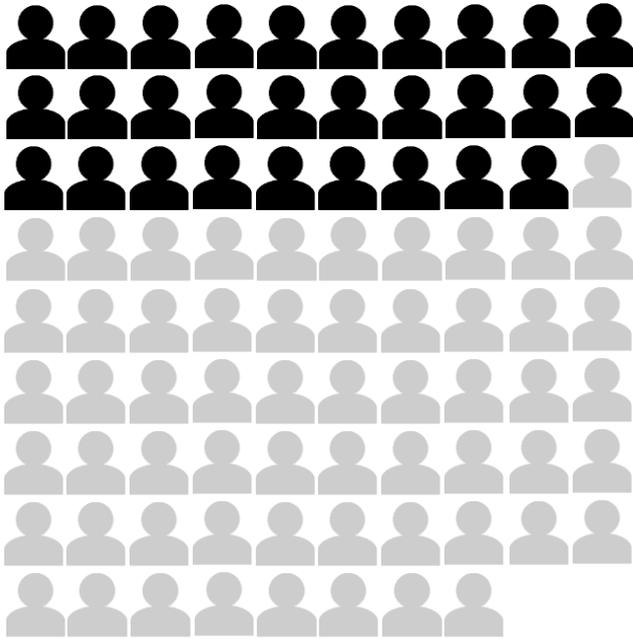
People with chronic hepatitis B virus infection are at increased risk for liver cancer and cirrhosis and are **70%–85% more likely to die prematurely than the general population.**

Bixler. Clin Infect Dis. 2019;68(6); Montuclard. J Hepatol. 2015;62(6); Beasley Lancet. 1981;2(8256); McMahon. Arch Intern Med. 1990;150(5)



There are
880,000
people living with
hepatitis B in the
U.S.

Roberts H, et al. Hepatology. 2021; Wong RJ, et al. Hepatology. 2021



**34% are aware
of their infection**

Roberts H, et al. Hepatology. 2021

Hepatitis B in the U.S. — a tale of two epidemiologies

- **People born outside the U.S.**

- Chronic infection since childhood



Roberts Hepatology 2021; Wong Hepatology 2021

Hepatitis B in the U.S. — a tale of two epidemiologies

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- Chronic infection since childhood

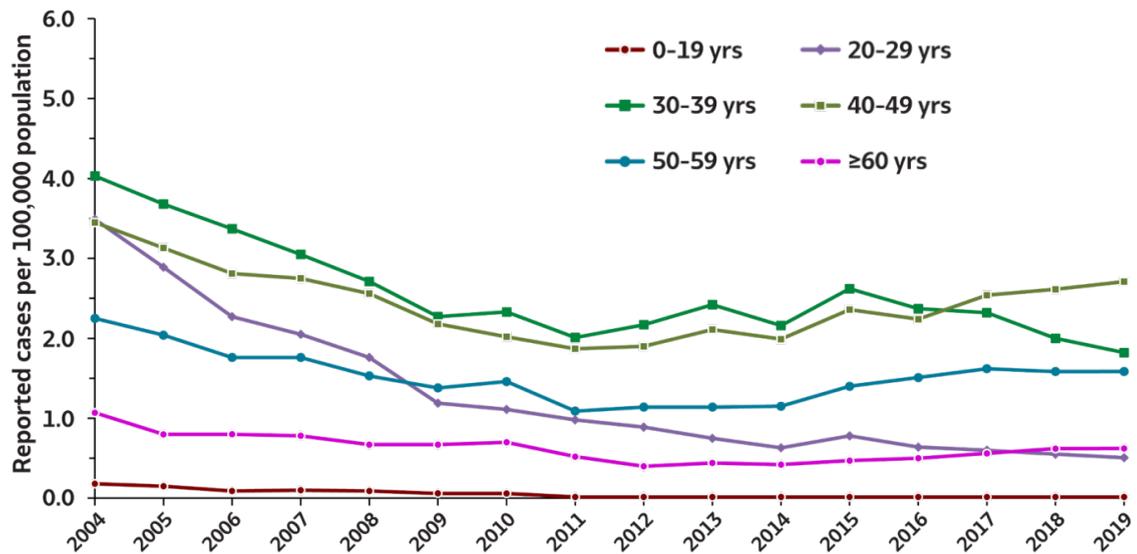
- **Unvaccinated people with behavioral risk factors**

- Injection drug use, unprotected sex
- Acute infections as adults, higher clearance rate



Roberts Hepatology 2021; Wong Hepatology 2021

New hepatitis B virus infections are in adults 19 years and up.



<https://www.cdc.gov/hepatitis/statistics/2019surveillance/pdfs/2019HepSurveillanceRpt.pdf>

From surveillance data - new hepatitis B virus infections are in adults 19 years of age and up.

- Rates have increased among adults over the age of 40
- Since 2011, the rate of acute infection among kids and adolescents 0-19 has been ~0/100,000

Current CDC recommendations are risk-based

Bridget
Co-infected
with HIV



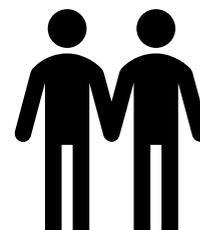
Charlie
Shares
Needles



Tran
Immigrant from
SE Asia



Thomas
Has sex with
multiple male
partners

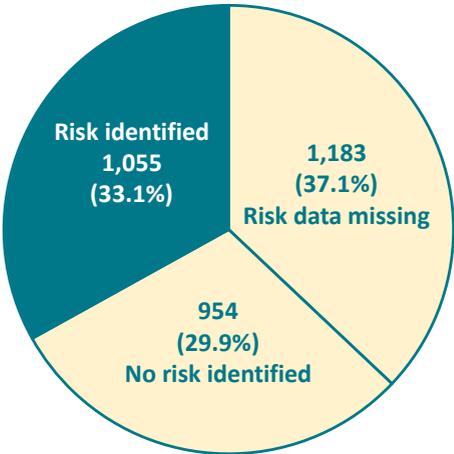


Adapted from: National Foundation for Infectious Diseases

Current CDC recommendations are risk-based.

- These may be difficult to implement in practice
- High proportion of people remain unaware of their infection
- Risk-based testing can often be stigmatizing and singles out groups that are already often marginalized.

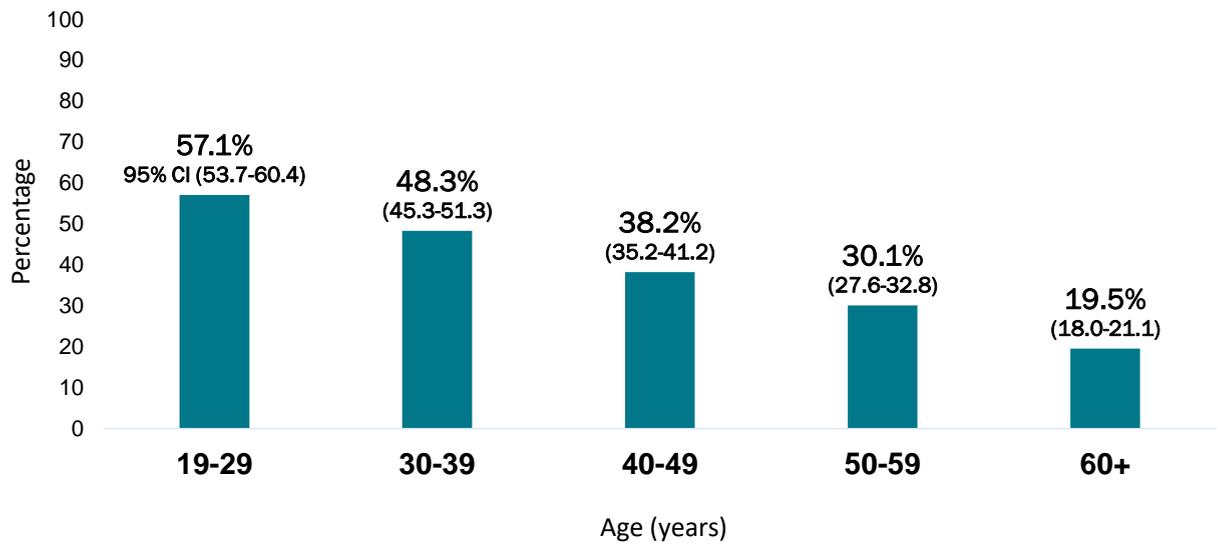
Limitations of a risk-based approach



2/3 of reported acute HBV cases were either missing risk data or reported no identified risk

<https://www.cdc.gov/hepatitis/statistics/2019surveillance/index.htm>

HepB Vaccination Coverage by Age in Adults with ≥ 1 Risk Factor



Lu et al. National Health Interview Survey, 2018. Unpublished 2021.

- Self-reported National Health Interview Survey data

Objective was to assess adding the following recommendations

- **Universal hepatitis B screening**
- **Risk-based testing of people with a history of:**
 - Incarceration
 - Hepatitis C virus infection
 - STIs or multiple sex partners
- **Screening with a three-test panel**

Methods

Activities of the CDC Guidelines Work Group

- **Developed research questions**
- **Conducted systematic reviews for:**
 - 1) expanding screening to all adults
 - 2) periodic testing for HBV infection among persons with:
 - HCV infection or
 - a history of incarceration.
- **Assessed the quality of the evidence**
- **Considered existing guidelines, systematic reviews, cost-effectiveness analyses, epidemiology data, ease of implementation, and potential harms.**



Universal Screening Systematic Review

- **How would adult universal screening for hepatitis B affect the number (and composition) of persons who screen positive for HBV infection?**

- Q1a. What is the prevalence of chronic HBV infection in the United States? In the general population, by age groups?
- Q1b. What is the yield (number of new diagnoses per tests performed) and sensitivity of alternative HBV screening strategies (e.g., universal versus targeted screening or screening strategies based on alternative risk factors)? [not assessed]

- The yield and sensitivity of different screening strategies was recently assessed by the US Preventive Services Taskforce

External Review

- **Peer reviewers:**

- Nominated by the American Association for the Study of Liver Diseases, Infectious Disease Society of America, and American College of Physicians
- <https://www.cdc.gov/hepatitis/policy/ISlreview/index.htm>

- **Federal Register Notice:**

- <https://www.regulations.gov/docket/CDC-2022-0044/document>

Cost-effectiveness analysis

The analysis compared current practice to current practice *plus* a one-time adult screening test.

▪ Current practice

- 33% of people with HBV infection diagnosed
 - 36% linked to care
 - 18% receive treatment

▪ Assumptions

- Prevalence undiagnosed chronic HBV infection: 0.24%
- HBsAg testing as part of healthcare visits
- Generic treatment

Toy et al. CID 2021; Harris et al. Am J Manag Care 2020; Patel et al. CID 2019.

Compared with current practice, universal screening of adults aged 18-79 years would avert

- 7 cases of compensated cirrhosis
- 3 cases of decompensated cirrhosis
- 5 cases of hepatocellular carcinoma
- 2 liver transplants
- 10 HBV related deaths



at a savings of \$200,334 per 100,000 adults screened.

NEEMA, Unpublished Sensitivity Analysis; Toy 2021

- The published paper by Dr. Toy and colleagues looked at screening adults aged 18-69.
- Here are results utilizing that same model, but increasing the upper bound of the age to 79.

Sensitivity analysis

- 3-test panel (HBsAg, anti-HBc, anti-HBs)
- Medicare reimbursement of \$28.27
- Incremental cost-effectiveness ratio (ICER) per quality adjusted life year (QALY)= \$11,207
- Cost-effective



Toy et al. CID 2021

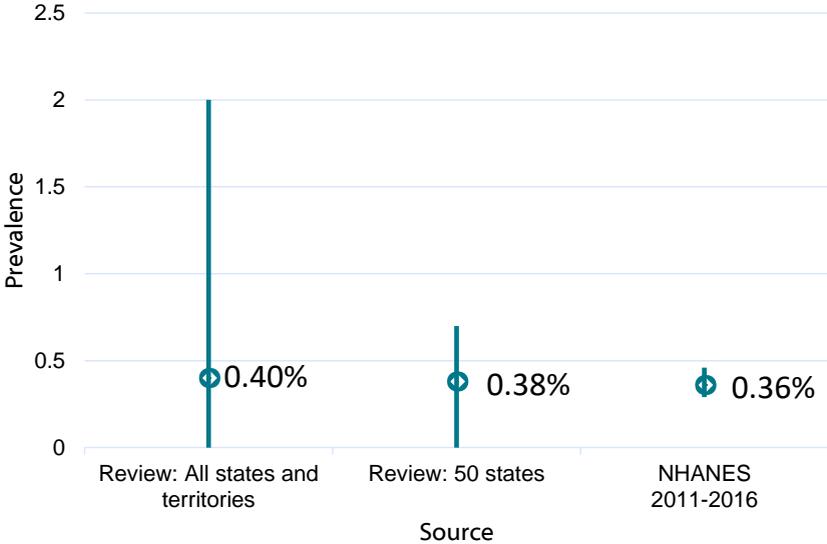
Universal Screening Systematic Review

Q1a. What is the prevalence of chronic HBV infection in the United States? In the general population, by age groups?

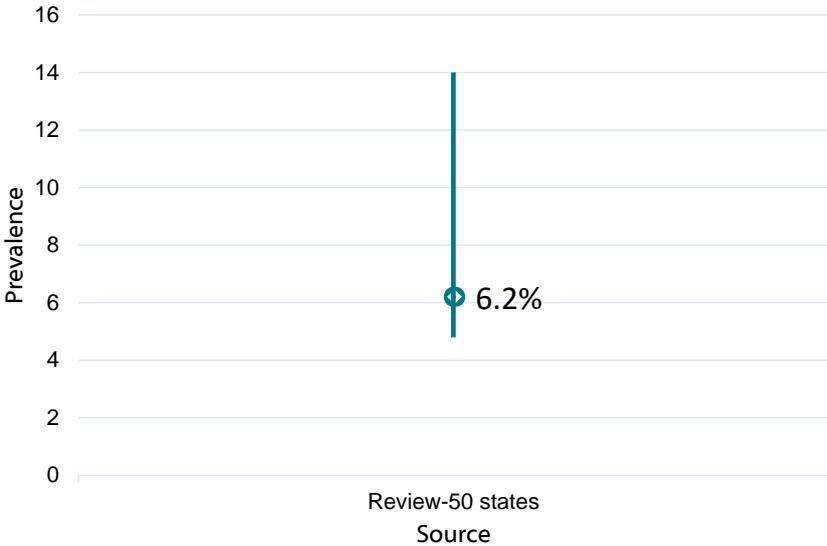
- **Restricted articles to the “general” population (N=17)**
 - Screening among people not suspected or known to be at increased risk of infection
- **Included studies among:**
 - First-time blood donors, organ donors, pregnant people, NHANES enrollees, and patients seeking care for a condition other than HBV infection

CDC, Unpublished

The median prevalence of chronic HBV infection in the general population was 0.4%.



The median prevalence of history of HBV infection (anti-HBc+) in the general population was 6.2%.



Justification for Screening

- ✓ HBV infection has significant morbidity and mortality
- ✓ Chronic infection can be detected before the onset of symptoms of liver disease using reliable and inexpensive screening tests
- ✓ Treatment for chronic HBV infection can reduce morbidity and mortality
- ✓ Screening can identify people who are at risk of HBV reactivation or who would benefit from vaccination
- ✓ Universal screening of adults is cost-effective

Proposed recommendation language

Screening Recommendations for Hepatitis B

- **Universal hepatitis B screening:**

- Hepatitis B screening at least once in a lifetime for adults ≥ 18 years. [\[New recommendation\]](#)

- **Screening pregnant persons**

- Hepatitis B screening for all pregnant people during each pregnancy, preferably in the first trimester, regardless of vaccination status or history of testing (Schillie et al. 2018).
- Pregnant adults aged ≥ 18 years should be screened with the 3-test panel unless they have received screening with the 3-test panel in the past [\[New recommendation\]](#).
- Adults with a history of 3-test panel screening and without subsequent risk can be tested for only HBsAg during pregnancy.

- **Risk-based testing**

- Testing for all individuals with a history of increased risk for HBV infection, regardless of age, if they were susceptible during the period of increased risk.
- Periodic testing for susceptible persons, regardless of age, with ongoing risk for exposure(s), while risk for exposures(s) persist. Offer testing if the risk for exposure occurred after previous HBV tests and while the person was susceptible.

The following persons have an increased risk for HBV infection:

- People currently or formerly incarcerated in a jail, prison, or other detention setting [*New recommendation*]
- People with a history of sexually transmitted infections or multiple sex partners [*New recommendation*]
- People with current or past hepatitis C virus infection [*New recommendation*]
- Anyone who requests hepatitis B testing [*New recommendation*]
- People born in regions with HBV prevalence $\geq 2\%$
- U.S.-born people not vaccinated as infants whose parents were born in regions with HBV prevalence $\geq 8\%$
- People with HIV infection
- People with current or past injection drug use
- Men who have sex with men
- Infants born to HBsAg positive persons
- Household, needle-sharing, or sexual contacts of people with known HBV infection
- Patients receiving predialysis, hemodialysis, peritoneal dialysis, or home dialysis
- People with elevated alanine aminotransferase or aspartate aminotransferase levels of unknown origin

Screening Recommendations for Hepatitis B

- Universal hepatitis B screening:
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- Screening pregnant persons
 - Hepatitis B screening for all pregnant people during each pregnancy, preferably in the first trimester, regardless of vaccination status or history of testing (Schillie et al. 2018).
 - Pregnant adults aged ≥ 18 years should be screened with the 3-test panel unless they have received screening with the 3-test panel in the past [\[New recommendation\]](#). Adults with a history of 3-test panel screening and without subsequent risk can be tested for only HBsAg during pregnancy.
- Risk-based testing
 - Testing for all individuals with a history of increased risk for HBV infection, regardless of age, if they were susceptible during the period of increased risk.
 - Periodic testing for susceptible persons, regardless of age, with ongoing risk for exposure(s), while risk for exposures(s) persist. Offer testing if the risk for exposure occurred after previous HBV tests and while the person was susceptible.
- **During screening, test for hepatitis B surface antigen (HBsAg), antibody to hepatitis B surface antigen (anti-HBs), and total [IgG and IgM] antibody to hepatitis B core antigen (total anti-HBc) [\[New recommendation\]](#)**

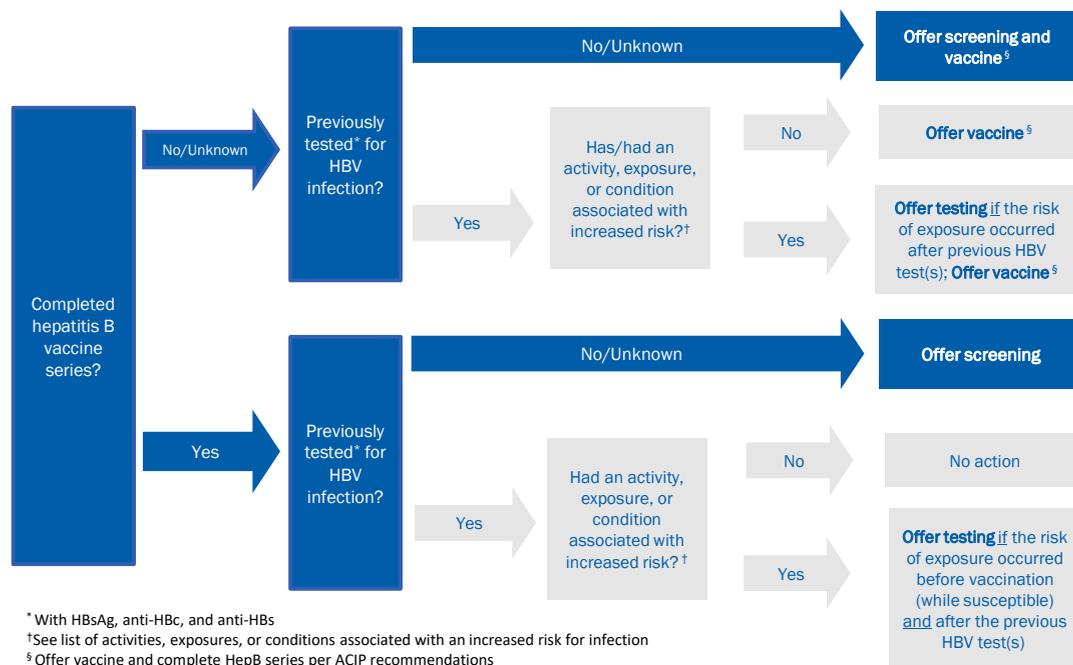
Interpretation of hepatitis B serologic test results

Clinical State	HBsAg	Anti-HBs	Total Anti-HBc	Action
Acute infection	Positive	Negative	Positive (IgM positive)	Link to hepatitis B care
Chronic infection	Positive	Negative	Positive (IgM negative)	Link to hepatitis B care
Resolved infection	Negative	Positive	Positive	Counsel
Immune from vaccination	Negative	Positive	Negative	Reassure if history of HepB vaccine series completion
Susceptible, never infected	Negative	Negative	Negative	Offer HepB vaccine if no history of HepB vaccine series completion
Isolated core antibody positive	Negative	Negative	Positive	Consult with specialist

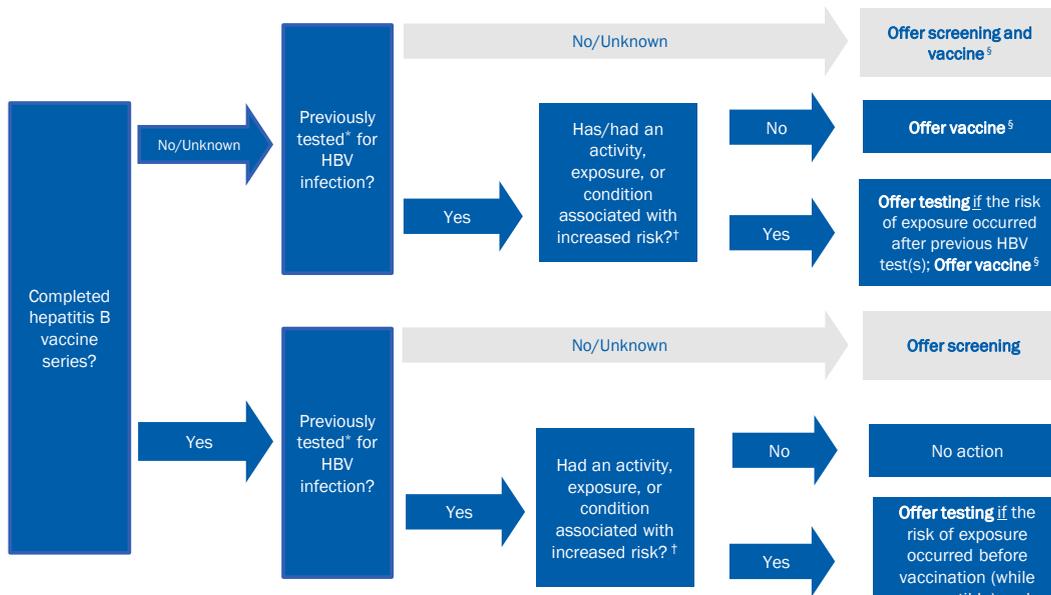
Clinical Considerations

- Clinical benefits of screening for individual patients who are ≥ 80 years of age
- Frequency of periodic testing should be a shared decision between the patient and provider based on individual risk factors and immune status.
- Having multiple sex partners can increase the risk for exposure to HBV and other STIs, but there is currently insufficient evidence to specify the number of sex partners and the time frame for screening to identify cases of chronic infection. Consider the number of partners, type of sex, and timing of last test when recommending testing for people with multiple sex partners.

Adults aged ≥ 18 years without a known history of HBV infection



Adults aged ≥ 18 years without a known history of HBV infection

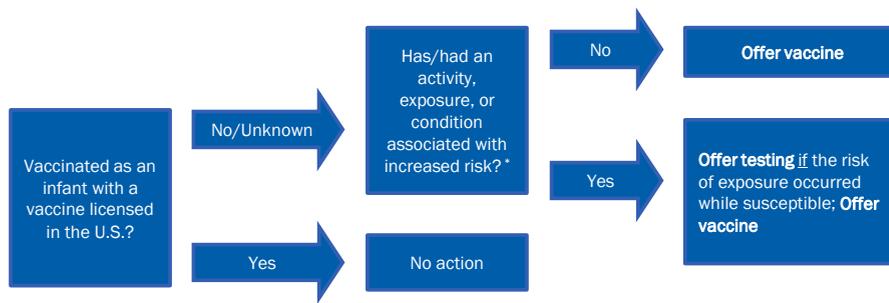


* With HBsAg, anti-HBc, and anti-HBs

† See list of activities, exposures, or conditions associated with an increased risk for infection

§ Offer vaccine and complete HepB series per ACIP recommendations

Children and adolescents aged 1–17 years without a known history of HBV infection



* See list of activities, exposures, or conditions associated with an increased risk for infection

New ACIP Recommendations



- The following groups *should* receive hepatitis B vaccines:
 - Adults aged 19 - 59 years
 - Adults aged ≥ 60 years with risk factors for hepatitis B
- The following groups *may* receive hepatitis B vaccines:
 - Adults aged ≥ 60 years without known risk factors for hepatitis B

Federal Register Notice

- Visit <https://www.regulations.gov/docket/CDC-2022-0044/> to view the full document draft and to submit a comment
 - Comment period is open through June 3, 2022
- All comments will be considered and responded to by the CDC workgroup

CDC Recommendations for Hepatitis B Screening and Testing – United States, 2022; Request for Comment

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NOTICE
CDC Recommendations for Hepatitis B Screening and Testing—United States, 2022
Agency Centers for Disease Control and Prevention | Posted Apr 4, 2022 | ID CDC-2022-0044-0001
Comment | Comments Due Jun 3, 2022

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SUPPORTING & RELATED MATERIAL
HBV Screening Guidelines
Agency Centers for Disease Control and Prevention | Posted Apr 4, 2022 | ID CDC-2022-0044-0005

SUPPORTING & RELATED MATERIAL
HBV Screening Guidelines_Supplement
Agency Centers for Disease Control and Prevention | Posted Apr 4, 2022 | ID CDC-2022-0044-0004

Next Steps

- **Spring 2022: Review and respond to peer review and FRN comments**
- **Summer 2022: Submit the revised guidelines to CDC clearance**
- **By end of 2022: MMWR publication**

Questions and Answers

- Please add any questions about the FRN process or clarification about the guidelines in the Q&A box, below.
- Visit <https://www.regulations.gov/docket/CDC-2022-0044/> to view the full document draft and to submit a comment
 - Comment period is open through June 3, 2022

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

